Loly G. Tor
(loly.tor@klgates.com)
**K&L Gates LLP**
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4026
(F) 973.848.4001

Anil H. Patel
(anil.patel@klgates.com)
*(pro hac vice)*
**K&L Gates LLP**
609 Main Street, Suite 4150
Houston, TX 77002
(T) 713.815.7300
(F) 713.815.7301

Devon C. Beane
(devon.beane@klgates.com)
*(pro hac vice)*
Ewa A. Wojciechowska
*(pro hac vice)*
**K&L Gates LLP**
70 West Madison Street, Suite 3300
Chicago, IL 60622
(T) 312.372.1121
(F) 312.827.8000

Peter Giunta
(peter.giunta@klgates.com)
**K&L Gates LLP**
599 Lexington Avenue
New York, NY 10022
(T) 212.536.3900
(F) 212.536.3901

Harold Storey
(harold.storey@klgates.com)
*(pro hac vice)*
Jenna Bruce
(jenna.bruce@klgates.com)
*(pro hac vice forthcoming)*
**K&L Gates LLP**
925 Fourth Avenue, Suite 2900
Seattle, WA 98104
(T) 206.623.7580
(F) 206.623.7022

*Attorneys for Defendants/Counterclaim-Plaintiffs*
*Cipla Limited and Cipla USA, Inc.*

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| THERAVANCE BIOPHARMA R&D IP, LLC, THERAVANCE BIOPHARMA US, INC., THERAVANCE BIOPHARMA IRELAND LIMITED, MYLAN IRELAND LIMITED, and MYLAN SPECIALTY L.P.,<br><br>Plaintiffs,<br><br>v.<br><br>EUGIA PHARMA SPECIALITIES LTD., EUGIA US LLC, AUROBINDO PHARMA | Case No. 1:23-cv-00926-KMW-AMD<br>(Consolidated)<br><br>**ANSWER TO PLAINTIFFS' FIRST AMENDED CONSOLIDATED COMPLAINT, SEPARATE DEFENSES AND COUNTERCLAIMS**<br><br>*Document Electronically Filed* |

USA, INC., AUROBINDO PHARMA LIMITED, MANKIND PHARMA LTD., LIFESTAR PHARMA LLC, ACCORD HEALTHCARE, INC., MEDICHEM S.A., MEDICHEM MANUFACTURING (MALTA) LTD., MEDICHEM USA, LLC, LUPIN INC., LUPIN PHARMACEUTICALS, INC., ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED, CIPLA LIMITED, and CIPLA USA, INC.,

Defendants.

Defendants Cipla Limited and Cipla USA, Inc. (collectively, "Cipla" or "Defendants"), by and through their attorneys, respond to each of the numbered paragraphs in the First Amended Consolidated Complaint for Patent Infringement by Plaintiffs Theravance Biopharma R&D IP, LLC, Theravance Biopharma Ireland Limited, Theravance Biopharma US, Inc., Mylan Ireland Limited, and Mylan Specialty L.P. (collectively, "Plaintiffs") as follows:

## NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 8,541,451 (the "'451 patent"), 9,765,028 (the "'028 patent"), 10,550,081 (the "'081 patent"), 11,008,289 (the "'289 patent"), 11,484,531 (the "'531 patent"), 11,691,948 (the "'948 patent") (collectively, the "Orange Book Patents-in-Suit"); 8,017,783 (the "'783 patent"), 9,249,099 (the "'099 patent"), 10,100,013 (the "'013 patent"), and 11,649,209 (the "'209 patent") (collectively with the Orange Book Patents-in-Suit, the "Patents-in-Suit"); and 8,754,225 (the "'225 patent") and 9,035,061 (the "'061 patent") (collectively, the "Colson Patents-in-Suit") arising under the Patent Laws of the United States, Title 35, United States Code, Section 1 *et seq.* This action relates to Abbreviated New Drug Application ("ANDA") No. 218089, filed by Mankind; ANDA No. 218100, filed by ACCORD *[REDACTED IN SERVICE COPY TO CIPLA]* Eugia; ANDA No. 218128, filed by Eugia; ANDA No. 218088, filed by Lupin; ANDA No. 217868, filed by Orbicular; and ANDA No. 217958, filed by Cipla, with the United States Food and Drug Administration ("FDA") for approval to market generic versions of YUPELRI® (revefenacin) inhalation solution, for oral inhalation, prior to the expiration of patents listed in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") for YUPELRI®.

**ANSWER:** Cipla admits that the Complaint purports to be based upon the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Cipla admits that Cipla Ltd. prepared and submitted

Abbreviated New Drug Application No. 217958 ("Cipla's ANDA") with the FDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or import of the product described in Cipla's ANDA ("Cipla's ANDA Product") before the expiration dates listed in the FDA's Orange Book for the '451 patent, the '028 patent, the '081 patent, the '289 patent, the '531 patent, and the '948 patent. Cipla denies the remaining allegations in Paragraph 1 of the First Amended Consolidated Complaint.

2. The following actions have been consolidated with this Action:**:**

- Civil Action No. 23-02843-KMW-AMD; consolidated with this Action on June 26, 2023 (D.I. 94); and
- Civil Action No. 23-06667-KMW-AMD; consolidated with this Action on September 29, 2023 (D.I. 125).

**ANSWER:** Admitted.

## THE PARTIES

### Plaintiffs

3. Plaintiff Theravance Biopharma R&D IP, LLC is a Delaware limited liability company having a principal place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080.

**ANSWER:** Upon information and belief, Cipla admits that Theravance Biopharma R&D IP, LLC has a place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 3 of the First Amended Consolidated Complaint, and therefore denies them.

4. Plaintiff Theravance Biopharma US, Inc. is a Delaware corporation having a principal place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080.

**ANSWER:** Upon information and belief, Cipla admits that Theravance Biopharma US, Inc. has a place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080. Cipla is

without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 4 of the First Amended Consolidated Complaint, and therefore denies them.

5. Plaintiff Theravance Biopharma Ireland Limited is an Irish company having a registered office at Ten Earlsfort Terrace, Dublin 2, D02 T380, Ireland.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 5 of the First Amended Consolidated Complaint, and therefore denies them.

6. Plaintiff Mylan Ireland Limited is a company having a principal place of business at Newenham Court, Northern Cross, Malahide Road, Dublin 17, Ireland; and a registered office at Unit 35/36, Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 6 of the First Amended Consolidated Complaint, and therefore denies them.

7. Plaintiff Mylan Specialty L.P. is a company having a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia, 26505.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 7 of the First Amended Consolidated Complaint, and therefore denies them.

8. Plaintiff Mylan Specialty L.P. sells YUPELRI® in this judicial district and throughout the United States.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 8 of the First Amended Consolidated Complaint, and therefore denies them.

9. Plaintiffs Mylan Specialty L.P. and Theravance Biopharma US, Inc. promote and market YUPELRI® in the United States.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 9 of the First Amended Consolidated Complaint, and therefore denies them.

10. Theravance Biopharma R&D IP, LLC is the assignee of the Patents-in-Suit. Theravance Biopharma R&D IP, LLC is a wholly owned subsidiary of Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that the U.S. Patent and Trademark Office assignment database lists Theravance Biopharma R&D IP, LLC as the assignee of the Patents-in-Suit. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 10 of the First Amended Consolidated Complaint, and therefore denies them.

11. Theravance Biopharma Ireland Limited is the exclusive licensee, and Mylan Ireland Limited is the exclusive sub-licensee, of the Patents-in-Suit. Mylan Ireland Limited is also the holder of approved New Drug Application No. 210598 for YUPELRI® (revefenacin) inhalation solution, for oral inhalation (the "YUPELRI® NDA").

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 11 of the First Amended Consolidated Complaint, and therefore denies them.

**Eugia**

12. On information and belief, Defendant Eugia Pharma is a company organized and existing under the laws of India, with its principal place of business at either its registered office at Maitrivihar, Plot #2, Ameerpet, Hyderabad, Telangana 500038, India ("Maitrivihar" address) or its corporate office at Galaxy, Floors: 22-24, Plot No.1, Sy No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Hyderabad, Telangana 500032, India ("Galaxy" address).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 12 of the First Amended Consolidated Complaint, and therefore denies them.

13. On information and belief, Eugia Pharma has on some occasions identified itself as Eugia Pharma "Specialities," and on other occasions as Eugia Pharma "Specialties," including, for

example, in Answers that Eugia Pharma filed in the following cases: Pfizer Inc. et al. v. Aurobindo Pharma, Ltd. et al., No. 20-cv-01528, Answer (D. Del. Dec 4, 2020) ("Eugia Pharma Specialities Ltd."; principal place of business at the "Maitrivihar" address); Medicure International, Inc. v. Aurobindo Pharma Ltd. et al., No. 2:21-cv-17534, Answer (D.N.J. Feb. 16, 2022) ("Eugia Pharma Specialties Limited"; principal place of business at the "Galaxy" address); Amgen Inc. et al. v. Aurobindo Pharma Ltd. et al., No. 22-cv-00227, Answer (D. Del. Mar 17, 2022) ("Eugia Pharma Specialties Limited"; principal place of business at the "Maitrivihar" address); and Aragon Pharms., Inc. et al. v. Eugia Pharma Specialities Ltd. et al., No. 2-22-cv-03186, Answer (D.N.J. May 26, 2022) ("Eugia Pharma Specialities Limited"; principal place of business at the "Maitrivihar" or "Galaxy" address).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 13 of the First Amended Consolidated Complaint, and therefore denies them.

14. On information and belief, Defendant Eugia US is a company organized and existing under the laws of Delaware, with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 14 of the First Amended Consolidated Complaint, and therefore denies them.

15. On information and belief, Eugia US is formerly known as AuroMedics Pharma LLC.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 15 of the First Amended Consolidated Complaint, and therefore denies them.

16. On information and belief, Defendant Aurobindo USA is a company organized and existing under the laws of Delaware, with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 16 of the First Amended Consolidated Complaint, and therefore denies them.

17. On information and belief, Defendant Aurobindo Ltd. is a company organized and existing under the laws of India, with its principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 17 of the First Amended Consolidated Complaint, and therefore denies them.

18. On information and belief, Eugia Pharma is a wholly owned subsidiary of Aurobindo Ltd.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 18 of the First Amended Consolidated Complaint, and therefore denies them.

19. On information and belief, Eugia US is a wholly owned subsidiary of Aurobindo Ltd.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 19 of the First Amended Consolidated Complaint, and therefore denies them.

20. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 20 of the First Amended Consolidated Complaint, and therefore denies them.

21. On information and belief, Eugia Pharma, Eugia US, Aurobindo USA, and Aurobindo Ltd. acted in concert to prepare and submit ANDA No. 218128 (the "Eugia ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Eugia ANDA Product"), for oral inhalation, prior to the expiration of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 21 of the First Amended Consolidated Complaint, and therefore denies them.

22. On information and belief, following any FDA approval of the Eugia ANDA, Eugia Pharma, Eugia US, Aurobindo USA, and Aurobindo Ltd. will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Eugia ANDA Product throughout the United States, including within the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 22 of the First Amended Consolidated Complaint, and therefore denies them.

**Mankind**

23. On information and belief, Defendant Mankind Pharma is a company organized and existing under the laws of India, with its principal place of business at 208, Okhla Industrial Estate, Phase III, New Delhi, 110020 India.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 23 of the First Amended Consolidated Complaint, and therefore denies them.

24. On information and belief, Defendant Lifestar is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 1200 MacArthur Blvd., Mahwah, New Jersey 07430.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 24 of the First Amended Consolidated Complaint, and therefore denies them.

25. On information and belief, Lifestar is a wholly owned subsidiary of Mankind Pharma.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 25 of the First Amended Consolidated Complaint, and therefore denies them.

26. On information and belief, Mankind Pharma and Lifestar acted in concert to prepare and submit ANDA No. 218089 (the "Mankind ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Mankind ANDA Product"), for oral inhalation, prior to the expiration of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 26 of the First Amended Consolidated Complaint, and therefore denies them.

27. On information and belief, following any FDA approval of the Mankind ANDA, Mankind Pharma and Lifestar will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Mankind ANDA Product throughout the United States, including within the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 27 of the First Amended Consolidated Complaint, and therefore denies them.

**Accord**

28. On information and belief, Defendant Accord is a company organized and existing under the laws of the State of North Carolina, with its principal place of business at 1009 Slater Road, Suite 210B, Durham, North Carolina 27703.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 28 of the First Amended Consolidated Complaint, and therefore denies them.

29. On information and belief, Accord Healthcare, Ltd. ("Accord Ltd.") is a company organized and existing under the laws of India, with its principal place of business at Near Sola Bridge, Sarkhej – Gandhinagar Highway, Thaltej, Ahmedabad, Gujarat 380054, India.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 29 of the First Amended Consolidated Complaint, and therefore denies them.

30. On information and belief, Intas Pharmaceuticals Ltd. ("Intas") is a company organized and existing under the laws of India, with its principal place of business at Near Sola Bridge, Sarkhej – Gandhinagar Highway, Thaltej, Ahmedabad, Gujarat 380054, India.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 30 of the First Amended Consolidated Complaint, and therefore denies them.

31. On information and belief, Accord is a wholly owned subsidiary of Intas.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 31 of the First Amended Consolidated Complaint, and therefore denies them.

32. On information and belief, Accord Ltd. is a wholly owned subsidiary of Intas.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 32 of the First Amended Consolidated Complaint, and therefore denies them.

33. On information and belief, Accord, Accord Ltd., and Intas acted in concert to prepare and submit ANDA No. 218100 (the "Accord ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Accord ANDA Product"), for oral inhalation, prior to the expiration of the Patents-in-Suit and Colson Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 33 of the First Amended Consolidated Complaint, and therefore denies them.

34. On information and belief, following any FDA approval of the Accord ANDA, Accord, Accord Ltd., and Intas will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Accord ANDA Product throughout the United States, including within the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 34 of the First Amended Consolidated Complaint, and therefore denies them.

**Medichem**

35. On information and belief, Defendant Medichem S.A. is a company organized and existing under the laws of Spain, with its principal place of business at Carrer de Fructuós Gelabert, 6, 08970 Sant Joan Despí, Barcelona, Spain.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 35 of the First Amended Consolidated Complaint, and therefore denies them.

36. On information and belief, Defendant Medichem Malta is a company organized and existing under the laws of Malta, with its principal place of business at HF 61, Hal Far Industrial Estate, Hal Far, Birzebuggia BBG 3000, Malta.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 36 of the First Amended Consolidated Complaint, and therefore denies them.

37. On information and belief, Defendant Medichem USA is a company organized and existing under the laws of the State of New Jersey, with its principal place of business at 50 Harrison St., Suite 217, Hoboken, New Jersey 07030.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 37 of the First Amended Consolidated Complaint, and therefore denies them.

38. On information and belief, Medichem Malta is a wholly owned subsidiary of Medichem S.A.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 38 of the First Amended Consolidated Complaint, and therefore denies them.

39. On information and belief, Medichem USA is a wholly owned subsidiary of Medichem S.A.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 39 of the First Amended Consolidated Complaint, and therefore denies them.

40. - 41. *[REDACTED IN SERVICE COPY TO CIPLA]*

**ANSWER:** Because Paragraphs 40-41 were sealed and redacted from the service copy of the First Amended Consolidated Complaint which Cipla received, Cipla deems that no answer to those paragraphs is necessary. To the extent such answer is required, Cipla denies Paragraphs 40-41.

**Lupin**

42. On information and belief, Defendant Lupin Inc. is a company organized and existing under the laws of the State of Delaware, with a place of business at 400 Campus Drive, Somerset, New Jersey 08873.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 42 of the First Amended Consolidated Complaint, and therefore denies them.

43. On information and belief, Lupin Ltd. is a company organized and existing under the laws of India, with its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex Bandra (E), Mumbai, 400051, India.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 43 of the First Amended Consolidated Complaint, and therefore denies them.

44. On information and belief, Defendant Lupin Pharmaceuticals is a company organized and existing under the laws of Delaware, with a place of business at 400 Campus Drive, Somerset, New Jersey 08873.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 44 of the First Amended Consolidated Complaint, and therefore denies them.

45. On information and belief, Lupin Inc. is a wholly owned subsidiary of Lupin Ltd.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 45 of the First Amended Consolidated Complaint, and therefore denies them.

46. On information and belief, Lupin Pharmaceuticals is a wholly owned subsidiary of Lupin Ltd.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 46 of the First Amended Consolidated Complaint, and therefore denies them.

47. On information and belief, Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals acted in concert to prepare and submit ANDA No. 218088 (the "Lupin ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Lupin ANDA Product"), for oral inhalation, prior to the expiration of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 47 of the First Amended Consolidated Complaint, and therefore denies them.

48. On information and belief, following any FDA approval of the Lupin ANDA, Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Lupin ANDA Product throughout the United States, including within the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 48 of the First Amended Consolidated Complaint, and therefore denies them.

**Orbicular**

49. On information and belief, Defendant Orbicular is a company organized and existing under the laws of India, with its principal place of business at Plot No. 53, ALEAP Industrial Estate, Pragathi Nagar, Kukatpally, Hyderabad, 500090, India.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 49 of the First Amended Consolidated Complaint, and therefore denies them.

50. On information and belief, Orbicular prepared and submitted ANDA No. 217868 (the "Orbicular ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Orbicular ANDA Product"), for oral inhalation, prior to the expiration of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 50 of the First Amended Consolidated Complaint, and therefore denies them.

51. On information and belief, following any FDA approval of the Orbicular ANDA, Orbicular will commercially manufacture, import, market, offer for sale, distribute, and/or sell the Orbicular ANDA Product throughout the United States, including within the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 51 of the First Amended Consolidated Complaint, and therefore denies them.

**Cipla**

52. On information and belief, Defendant Cipla Ltd. is a company organized and existing under the laws of India, with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

**ANSWER:** Admitted.

53. On information and belief, Defendant Cipla USA is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

**ANSWER:** Admitted.

54. On information and belief, Cipla USA is a wholly owned subsidiary of Cipla Ltd.

**ANSWER:** Admitted.

55. On information and belief, Cipla Ltd. and Cipla USA acted in concert to prepare and submit ANDA No. 217958 (the "Cipla ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Cipla ANDA Product"), for oral inhalation, prior to the expiration of the Patents-in-Suit.

**ANSWER:** Cipla admits that Cipla Ltd. prepared and submitted Cipla's ANDA with the FDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or import of Cipla's ANDA Product. Cipla denies the remaining allegations and characterizations contained in Paragraph 55 of the First Amended Consolidated Complaint.

56. On information and belief, following any FDA approval of the Cipla ANDA, Cipla Ltd. and Cipla USA will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Cipla ANDA Product throughout the United States, including within the State of New Jersey.

**ANSWER:** Cipla denies the allegations of Paragraph 56 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

## JURISDICTION AND VENUE

57. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

58. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., including 35 U.S.C. § 271.

**ANSWER:** Cipla admits that the First Amended Complaint purports to be based upon the patent laws of the United States, 35 U.S.C. § 1, *et seq*., including 35 U.S.C. § 271.

59. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 28 U.S.C. §§ 2201 and 2202.

**ANSWER:** Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest subject matter jurisdiction over the Patents-in-Suit for the limited purposes of this litigation. Cipla denies the remaining allegations of Paragraph 59.

**Eugia**

60. This Court has personal jurisdiction over Eugia US at least because, on information and belief, Eugia US is a corporation with its principal place of business in the State of New Jersey, at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 60 of the First Amended Consolidated Complaint, and therefore denies them.

61. This Court has personal jurisdiction over Aurobindo USA at least because, on information and belief, Aurobindo USA is a corporation with its principal place of business in the State of New Jersey, at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 61 of the First Amended Consolidated Complaint, and therefore denies them.

62. This Court has personal jurisdiction over Eugia Pharma at least because, on information and belief, Eugia Pharma directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 62 of the First Amended Consolidated Complaint, and therefore denies them.

63. This Court has personal jurisdiction over Eugia US at least because, on information and belief, Eugia US directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 63 of the First Amended Consolidated Complaint, and therefore denies them.

64. This Court has personal jurisdiction over Aurobindo USA at least because, on information and belief, Aurobindo USA directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 64 of the First Amended Consolidated Complaint, and therefore denies them.

65. This Court has personal jurisdiction over Aurobindo Ltd. at least because, on information and belief, Aurobindo Ltd. directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 65 of the First Amended Consolidated Complaint, and therefore denies them.

66. This Court has personal jurisdiction over Eugia Pharma, Eugia US, Aurobindo USA, and Aurobindo Ltd. at least because, *inter alia*, on information and belief, (1) Eugia Pharma itself, and/or in concert with Eugia US, Aurobindo Ltd. and/or Aurobindo USA, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Eugia ANDA Product in the United States, including the State of New Jersey; and (2) Eugia Pharma itself, and/or in concert with Eugia US, Aurobindo Ltd. and/or Aurobindo USA, will market, distribute, offer for sale, and/or sell the Eugia ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218128, and Eugia will derive substantial revenue from the use or consumption of the Eugia ANDA Product in the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 66 of the First Amended Consolidated Complaint, and therefore denies them.

67. If Eugia Pharma's connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Eugia Pharma is not

subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Eugia Pharma in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 67 of the First Amended Consolidated Complaint, and therefore denies them.

68. If Aurobindo Ltd.'s connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Aurobindo Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Aurobindo Ltd. in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 68 of the First Amended Consolidated Complaint, and therefore denies them.

69. On information and belief, Eugia US is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration No. 5004299.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 69 of the First Amended Consolidated Complaint, and therefore denies them.

70. On information and belief, Aurobindo USA is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration Nos. 5003120 and 5005256.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 70 of the First Amended Consolidated Complaint, and therefore denies them.

71. On information and belief, Aurobindo USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0100921223.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 71 of the First Amended Consolidated Complaint, and therefore denies them.

72. Venue is proper in this district for Eugia Pharma pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Eugia Pharma is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 72 of the First Amended Consolidated Complaint, and therefore denies them.

73. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Eugia US at least because, on information and belief, Eugia US has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Eugia US has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in-Suit that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Eugia ANDA in the State of New Jersey and/or with the intention of seeking to market the Eugia ANDA Product nationwide, including within the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 73 of the First Amended Consolidated Complaint, and therefore denies them.

74. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Aurobindo USA at least because, on information and belief, Aurobindo USA has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Aurobindo USA has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in-Suit that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Eugia ANDA in the State of New Jersey and/or with the intention of seeking to market the Eugia ANDA Product nationwide, including within the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 74 of the First Amended Consolidated Complaint, and therefore denies them.

75. Venue is proper in this district for Aurobindo Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Aurobindo Ltd. is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 75 of the First Amended Consolidated Complaint, and therefore denies them.

76. On information and belief, Eugia Pharma, Aurobindo USA, and Aurobindo Ltd. have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and have not contested jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See*, *e.g.*, *Eisai Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, No. 1-22-cv-03610 (D.N.J. June 8, 2022) (Aurobindo USA and Aurobindo Ltd.); *Aragon Pharms., Inc. et al. v. Eugia Pharma Specialities Ltd. et al.*, No. 2-22-cv-03186 (D.N.J. May 26, 2022) (Eugia Pharma and Aurobindo USA); *Medicure International, Inc. v. Aurobindo Pharma Ltd. et al.*, No. 2-21-cv-17534 (D.N.J. Sept. 24, 2021) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2-21-cv-00624 (D.N.J. Jan. 12, 2021) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Merck Sharp & Dohme BV et al. v. Aurobindo Pharma USA, Inc. et al.*, No. 2-20-cv-02576 (D.N.J. Mar. 10, 2020) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2-20-cv-00315 (D.N.J. Jan. 8, 2020) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2-19-cv-05799 (D.N.J. Feb. 14, 2019) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Boehringer Ingelheim Pharms., Inc. et al. v. Aurobindo Pharma USA Inc. et al.*, No. 3-17-cv-07887 (D.N.J. Oct. 4, 2017) (Eugia Pharma and Aurobindo USA) (also filed a counterclaim); *Celgene Corp. v. Hetero Labs Ltd. et al.*, No. 2-17-cv-03387 (D.N.J. May 11, 2017) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 76 of the First Amended Consolidated Complaint, and therefore denies them.

**Mankind**

77. This Court has personal jurisdiction over Lifestar at least because, on information and belief, Lifestar is a corporation with its principal place of business in New Jersey, at 1200 MacArthur Blvd, Mahwah, New Jersey 07430.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 77 of the First Amended Consolidated Complaint, and therefore denies them.

78. This Court has personal jurisdiction over Mankind Pharma at least because, on information and belief, Mankind Pharma directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 78 of the First Amended Consolidated Complaint, and therefore denies them.

79. This Court has personal jurisdiction over Lifestar at least because, on information and belief, Lifestar directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 79 of the First Amended Consolidated Complaint, and therefore denies them.

80. This Court has personal jurisdiction over Mankind Pharma and Lifestar at least because, *inter alia*, on information and belief, (1) Mankind Pharma itself, and/or in concert with its wholly owned subsidiary Lifestar, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Mankind ANDA Product in the United States, including the State of New Jersey; and (2) Mankind Pharma itself, and/or in concert with its wholly owned subsidiary Lifestar, will market, distribute, offer for sale, and/or sell the Mankind ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218089, and Mankind will derive substantial revenue from the use or consumption of the Mankind ANDA Product in the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 80 of the First Amended Consolidated Complaint, and therefore denies them.

81. If Mankind Pharma's connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Mankind Pharma is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction

over Mankind Pharma in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 81 of the First Amended Consolidated Complaint, and therefore denies them.

82. On information and belief, Lifestar is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration No. 5005074.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 82 of the First Amended Consolidated Complaint, and therefore denies them.

83. On information and belief, Lifestar is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0450064472.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 83 of the First Amended Consolidated Complaint, and therefore denies them.

84. Venue is proper in this district for Mankind Pharma pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, on information and belief, Mankind Pharma is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 84 of the First Amended Consolidated Complaint, and therefore denies them.

85. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Lifestar at least because, on information and belief, Lifestar has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Lifestar has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in Suit that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Mankind ANDA in the State of New Jersey and/or with the intention of seeking to market the Mankind ANDA Product nationwide, including within the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 85 of the First Amended Consolidated Complaint, and therefore denies them.

86. On information and belief, Mankind Pharma and Lifestar have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and did not contest jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See*, *e.g.*, *Bayer Intellectual Property GmbH et al. v. Mankind Pharma Ltd.*, No. 22-cv-05599 (D.N.J. Sept. 16, 2022) (Mankind Pharma); *Merck Sharp & Dohme B.V. et al. v. Mankind Pharma Ltd. et al.*, No. 2:20-cv-02787 (D.N.J. Mar. 13, 2020) (Mankind Pharma and Lifestar); *Celgene Corp. v. Mankind Pharma Ltd. et al.*, No. 3:18-cv-11081 (D.N.J. June 26, 2018) (Mankind Pharma) (also filed a counterclaim).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 86 of the First Amended Consolidated Complaint, and therefore denies them.

**Accord**

87. This Court has personal jurisdiction over Accord at least because, on information and belief, Accord directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 87 of the First Amended Consolidated Complaint, and therefore denies them.

88. This Court also has personal jurisdiction over Accord at least because Accord has expressly consented to personal jurisdiction in this District for purposes of this Action. (D.I. 18.)

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 88 of the First Amended Consolidated Complaint, and therefore denies them.

89. This Court has personal jurisdiction over Accord at least because, inter alia, on information and belief, (1) Accord itself, and/or in concert with Intas and/or Accord Ltd., has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product in the United States, including the

State of New Jersey; and (2) Accord itself, and/or in concert with Intas and/or Accord Ltd., will market, distribute, offer for sale, and/or sell the Accord ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218100, and Accord will derive substantial revenue from the use or consumption of the Accord ANDA Product in the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 89 of the First Amended Consolidated Complaint, and therefore denies them.

90. On information and belief, Intas, Accord, and Accord Ltd. operate as a single integrated business. Accord's website indicates that "Accord Healthcare, Inc., the US subsidiary of Intas Pharmaceuticals, is a leading generic pharmaceutical company . . . . Through its subsidiaries, Intas markets its products in 85 countries." *See* https://www.accordhealthcare.us/#:~:text=Accord%20Healthcare%2C%20Inc.%2C%20the,its%20products%20in%2085%20countries (accessed December 4, 2023).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 90 of the First Amended Consolidated Complaint, and therefore denies them.

91. Venue is proper as to Accord pursuant to 28 U.S.C. §§ 1391 and/or 1400(b). See Eagle Pharms., Inc. et al. v. Accord Healthcare Inc., No. 2:19-cv-09031, Answer, Dkt. 11 at 4 (D.N.J. Mar. 27, 2019) ("Accord does not contest venue in this case.").

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 91 of the First Amended Consolidated Complaint, and therefore denies them.

92. Venue is also proper as to Accord because Accord has expressly consented to venue in this District for purposes of this Action. (D.I. 18.)

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 92 of the First Amended Consolidated Complaint, and therefore denies them.

93. On information and belief, Accord has litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and has not contested jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See,*

*e.g., Eagle Pharms., Inc., et al. v. Accord Healthcare Inc.*, No. 2-19-cv-09031 (D.N.J. Mar. 27, 2019); *Sumitomo Dainippon Pharma Co., Ltd., et al. v. Aurobindo Pharma Ltd., et al.*, No. 2-18-cv-02620 (D.N.J. Feb. 23, 2018); *Otsuka Pharms. Co., Ltd., v. Intas Pharms. Ltd., et al.*, No. 1:16-cv-05743 (D.N.J. Sept. 19, 2016) (also filed a counterclaim); *Sanofi-Aventis US LLC v. Accord Healthcare, Inc.*, No. 3-14-cv-08079 (D.N.J. Dec. 29, 2014) (also filed a counterclaim); *Otsuka Pharm. Co. v. Intas Pharms. Ltd., et al.*, No. 1-14-cv-03996 (D.N.J. Jun. 20, 2014) (also filed a counterclaim).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 93 of the First Amended Consolidated Complaint, and therefore denies them.

**Medichem**

94. This Court has personal jurisdiction over Medichem USA at least because, on information and belief, Medichem USA is a corporation with a place of business in the State of New Jersey, at 50 Harrison St, Suite 217, Hoboken, New Jersey 07030.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 94 of the First Amended Consolidated Complaint, and therefore denies them.

95. This Court has personal jurisdiction over Medichem S.A. at least because, on information and belief, Medichem S.A. directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 95 of the First Amended Consolidated Complaint, and therefore denies them.

96. This Court has personal jurisdiction over Medichem S.A. at least because, on information and belief, Medichem S.A. has continuous and systematic contacts with this judicial district through its wholly owned subsidiary, Medichem USA, which has a principal place of business at Hoboken Business Center, 50 Harrison St. #217, Hoboken, New Jersey, which directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 96 of the First Amended Consolidated Complaint, and therefore denies them.

97. This Court has personal jurisdiction over Medichem Malta at least because, on information and belief, Medichem Malta directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 97 of the First Amended Consolidated Complaint, and therefore denies them.

98. On information and belief, Medichem is a vertically integrated company including Medichem S.A., Medichem Malta, and Medichem USA. See, e.g., https://www.medichem.es/ (accessed December 4, 2023) ("Medichem is a vertically integrated pharmaceutical company . . . [that] specialize[s] in the development and manufacture of APIs and FDFs for the global generics industry. . . . Medichem is headquartered in Spain, with a team of around 400 talented individuals in locations including the USA . . . ."); https://www.linkedin.com/company/medichem (accessed December 4, 2023) ("Medichem is a vertically integrated pharmaceutical company. . . . Medichem is headquartered in Spain, with a team of over 450 talented individuals in locations including the USA, Malta and China."); https://www.medichem.es/manufacturing-solutions/ (accessed December 4, 2023) ("By achieving vertical integration, Medichem controls and owns all the elements of its value chain that play a role in its manufacturing process."); *[REDACTED IN SERVICE COPY TO CIPLA]*.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 98 of the First Amended Consolidated Complaint, and therefore denies them.

99. On information and belief, in 2021, Medichem advertised and promoted its generic revefenacin product as one of its "Dossiers under Development" and as a "vertically integrated [API / FDF]" in its 2021 "Portfolio." See https://www.medichem.es/wp-content/uploads/2020/07/portfolio.pdf (accessed December 4, 2023).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 99 of the First Amended Consolidated Complaint, and therefore denies them.

100. On information and belief, Medichem currently advertises and promotes its generic revefenacin product as a "vertically integrated [API / FDF]" on its 2023 "Product List." See https://www.medichem.es/wp-content/uploads/2023/03/230316-Medichem Product-List-Digital-A4-Hr-Interactive-V8-1.pdf (accessed December 4, 2023).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 100 of the First Amended Consolidated Complaint, and therefore denies them.

101. - 102. *[REDACTED IN SERVICE COPY TO CIPLA]*

**ANSWER:** Because Paragraphs 101-102 were sealed and redacted from the service copy of the First Amended Consolidated Complaint which Cipla received, Cipla deems that no answer to those paragraphs is necessary. To the extent such answer is required, Cipla denies Paragraphs 101-102.

103. If Medichem S.A.'s connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Medichem S.A. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Medichem S.A. in the State of New Jersey is consistent with the United States Constitution and laws. See Fed. R. Civ. P. 4(k)(2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 103 of the First Amended Consolidated Complaint, and therefore denies them.

104. If Medichem Malta's connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Medichem Malta is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Medichem Malta in the State of New Jersey is consistent with the United States Constitution and laws. See Fed. R. Civ. P. 4(k)(2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 104 of the First Amended Consolidated Complaint, and therefore denies them.

105. On information and belief, Medichem USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0600438204.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 105 of the First Amended Consolidated Complaint, and therefore denies them.

106. Venue is proper in this district for Medichem S.A. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, inter alia, on information and belief, Medichem S.A. is a foreign corporation organized and existing under the laws of Spain and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 106 of the First Amended Consolidated Complaint, and therefore denies them.

107. Venue is proper in this district for Medichem Malta pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, inter alia, on information and belief, Medichem Malta is a foreign corporation organized and existing under the laws of Malta and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 107 of the First Amended Consolidated Complaint, and therefore denies them.

108. *[REDACTED IN SERVICE COPY TO CIPLA]*

**ANSWER:** Because Paragraph 108 was sealed and redacted from the service copy of the First Amended Consolidated Complaint which Cipla received, Cipla deems that no answer to this paragraphs is necessary. To the extent such answer is required, Cipla denies Paragraph 108.

**Lupin**

109. This Court has personal jurisdiction over Lupin Inc. at least because, on information and belief, Lupin Inc. is a corporation with a place of business in the State of New Jersey, at 400 Campus Drive, Somerset, New Jersey 08873.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 109 of the First Amended Consolidated Complaint, and therefore denies them.

110. This Court has personal jurisdiction over Lupin Pharmaceuticals at least because, on information and belief, Lupin Pharmaceuticals is a corporation with a place of business in the State of New Jersey, at 400 Campus Drive, Somerset, New Jersey 08873.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 110 of the First Amended Consolidated Complaint, and therefore denies them.

111. This Court also has personal jurisdiction over Lupin Inc. and Lupin Pharmaceuticals at least because Lupin Inc. and Lupin Pharmaceuticals have expressly consented to personal jurisdiction in this District for purposes of this Action. (D.I. 21.)

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 111 of the First Amended Consolidated Complaint, and therefore denies them.

112. This Court has personal jurisdiction over Lupin Inc. at least because, on information and belief, Lupin Inc. directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 112 of the First Amended Consolidated Complaint, and therefore denies them.

113. This Court has personal jurisdiction over Lupin Pharmaceuticals at least because, on information and belief, Lupin Pharmaceuticals directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 113 of the First Amended Consolidated Complaint, and therefore denies them.

114. This Court has personal jurisdiction over Lupin Inc. and Lupin Pharmaceuticals at least because, *inter alia*, on information and belief, (1) Lupin Inc. itself, and/or in concert with Lupin Ltd. and/or Lupin Pharmaceuticals, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin ANDA Product in the United States, including the State of New Jersey; and (2) Lupin Inc. itself, and/or in concert with Lupin Ltd. and/or Lupin Pharmaceuticals, will market, distribute, offer for sale, and/or sell the Lupin ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218088, and Lupin will derive substantial revenue from the use or consumption of the Lupin ANDA Product in the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 114 of the First Amended Consolidated Complaint, and therefore denies them.

115. On information and belief, Lupin Pharmaceuticals is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration Nos. 5004060 and 5005159.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 115 of the First Amended Consolidated Complaint, and therefore denies them.

116. On information and belief, Lupin Pharmaceuticals is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID Nos. 0100953673 and 0101043376.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 116 of the First Amended Consolidated Complaint, and therefore denies them.

117. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Lupin Inc. at least because, on information and belief, Lupin Inc. has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Lupin Inc. has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in-Suit that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Lupin ANDA in the State of New Jersey and/or with the intention of seeking to market the Lupin ANDA Product nationwide, including within the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 117 of the First Amended Consolidated Complaint, and therefore denies them.

118. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Lupin Pharmaceuticals at least because, on information and belief, Lupin Pharmaceuticals has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Lupin Pharmaceuticals has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in-Suit that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Lupin ANDA in the State of New Jersey and/or with the intention of seeking to market the Lupin ANDA Product nationwide, including within the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 118 of the First Amended Consolidated Complaint, and therefore denies them.

119. Venue is also proper as to Lupin Inc. and Lupin Pharmaceuticals because Lupin Inc. and Lupin Pharmaceuticals have expressly consented to venue in this District for purposes of this Action. (D.I. 21.)

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 119 of the First Amended Consolidated Complaint, and therefore denies them.

120. On information and belief, Lupin Inc. and/or Lupin Pharmaceuticals have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and have not contested jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See*, *e.g.*, *Aragon Pharms., Inc. et al. v. Lupin Ltd. et al.*, No. 2-22-cv-02825 (D.N.J. May 13, 2022) (Lupin Pharmaceuticals) (also filed a counterclaim); *Jazz Pharm., Inc. v. Lupin Ltd.*, No. 2-22-cv-02773 (D.N.J. May 11, 2022) (Lupin Inc.) (also filed a counterclaim); *Bausch Health Ireland Ltd. f/k/a Valeant Pharms. Ireland Ltd. et al. v. Lupin Ltd. et al.*, No. 1-20-cv-11039 (D.N.J. Aug. 21, 2020) (Lupin Inc.) (also filed a counterclaim); *Horizon Orphan LLC et al. v. Lupin Ltd. et al.*, No. 2-20-cv-10339 (D.N.J. Aug. 11, 2020) (Lupin Pharmaceuticals); *Bristol-Myers Squibb Co. v. Lupin Ltd. et al.*, No. 3-20-cv-07810 (D.N.J. Jun. 25, 2020) (Lupin Inc.) (also filed a counterclaim).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 120 of the First Amended Consolidated Complaint, and therefore denies them.

**Orbicular**

121. This Court has personal jurisdiction over Orbicular at least because, on information and belief, Orbicular directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 121 of the First Amended Consolidated Complaint, and therefore denies them.

122. This Court has personal jurisdiction over Orbicular at least because, *inter alia*, on information and belief, (1) Orbicular filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Orbicular ANDA Product in the United States, including the State of New Jersey; and (2) Orbicular will market, distribute, offer for sale, and/or sell the Orbicular ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 217868, and Orbicular will derive substantial revenue from the use or consumption of the Orbicular ANDA Product in the State of New Jersey.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 122 of the First Amended Consolidated Complaint, and therefore denies them.

123. If Orbicular's connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Orbicular is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Orbicular in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 123 of the First Amended Consolidated Complaint, and therefore denies them.

124. Venue is proper in this district for Orbicular pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Orbicular is a foreign corporation

organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 124 of the First Amended Consolidated Complaint, and therefore denies them.

125. On information and belief, Orbicular has litigated a previous Hatch-Waxman patent infringement dispute in the District of New Jersey and did not contest jurisdiction and venue in the District of New Jersey in a prior case arising out of the filing of an ANDA filing. *See Aerie Pharm., Inc. et al. v. Orbicular Pharm. Techs.*, No. 3-22-cv-01364 (D.N.J. Mar. 14, 2022).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 125 of the First Amended Consolidated Complaint, and therefore denies them.

**Cipla**

126. This Court has personal jurisdiction over Cipla USA at least because, on information and belief, Cipla USA is a corporation with its principal place of business in the State of New Jersey, at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

**ANSWER:** Paragraph 126 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest personal jurisdiction over Cipla USA in this Court for the limited purposes of this litigation. Cipla admits that Cipla USA has a principal place of business in the State of New Jersey, at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

127. This Court has personal jurisdiction over Cipla Ltd. at least because, on information and belief, Cipla Ltd. directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Paragraph 127 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest personal jurisdiction over Cipla Ltd. in this Court for the limited purposes of this litigation. Cipla further admits that Cipla Ltd. is in the business of developing, manufacturing, and selling pharmaceutical drug

products, including generic drug products, in the United States. Cipla denies the remaining allegations of Paragraph 127.

128. This Court has personal jurisdiction over Cipla USA at least because, on information and belief, Cipla USA directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

**ANSWER:** Paragraph 128 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest personal jurisdiction in this Court for the limited purposes of this litigation. Cipla further admits that Cipla USA is in the business of marketing, and selling pharmaceutical drug products, including generic drug products, in the United States. Cipla denies the remaining allegations of Paragraph 128.

129. This Court has personal jurisdiction over Cipla Ltd. and Cipla USA at least because, *inter alia*, on information and belief, (1) Cipla Ltd. itself, and/or in concert with its wholly owned subsidiary and agent Cipla USA, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product in the United States, including the State of New Jersey; and (2) Cipla Ltd. itself, and/or in concert with its wholly owned subsidiary and agent Cipla USA, will market, distribute, offer for sale, and/or sell the Cipla ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 217958, and Cipla will derive substantial revenue from the use or consumption of the Cipla ANDA Product in the State of New Jersey.

**ANSWER:** Paragraph 129 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited or Cipla USA, Inc. for the limited purposes of this litigation. Cipla further admits that Cipla Limited prepared and submitted Cipla's ANDA seeking approval from the FDA to market and sell Cipla's ANDA Product in the United States. Cipla denies the remaining allegations of Paragraph 129.

130. If Cipla Ltd.'s connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Cipla Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Cipla Ltd. in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

**ANSWER:** Paragraph 130 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest this Court's jurisdiction over Cipla Ltd. for the limited purposes of this litigation. Cipla denies the remaining allegations of Paragraph 130.

131. On information and belief, Cipla USA is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration No. 5005183.

**ANSWER:** Admitted.

132. On information and belief, Cipla USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0450318628.

**ANSWER:** Admitted.

133. Venue is proper in this district for Cipla Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Cipla Ltd. is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

**ANSWER:** Paragraph 133 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue in this Court for the limited purposes of this litigation. Cipla admits that Cipla Limited is a foreign corporation. Cipla denies the remaining allegations of Paragraph 133.

134. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Cipla USA at least because, on information and belief, Cipla USA has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Cipla USA has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in Suit that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Cipla ANDA in the State of New Jersey and/or with the intention of seeking to market the Cipla ANDA Product nationwide, including within the State of New Jersey.

**ANSWER:** Paragraph 134 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue in this Court for the limited purposes of this litigation. Cipla admits that Cipla USA is a corporation

organized and existing under the laws of the State of New Jersey. Cipla denies the remaining allegations of Paragraph 134.

135. On information and belief, Cipla Ltd. and Cipla USA have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and did not contest jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See*, *e.g.*, *Par Pharm., Inc. et al. v. Cipla Ltd. et al.*, No. 2-22-cv-02814 (D.N.J. May 13, 2022) (Cipla Ltd. and Cipla USA) (also filed a counterclaim); *Teva Branded Pharm. Prods. R&D, Inc. et al. v. Cipla Ltd.*, No. 2-20-cv-14890 (D.N.J. Oct. 23, 2020) (Cipla Ltd.) (also filed a counterclaim); *Teva Branded Pharm. Prods. R&D, Inc. et al. v. Cipla Ltd.*, No. 2-20-cv-10172 (D.N.J. Aug. 7, 2020) (Cipla Ltd.) (also filed a counterclaim); *Celgene Corp. v. Cipla Ltd.*, No. 2-20-cv-07759 (D.N.J. Jun. 24, 2020) (Cipla Ltd.) (also filed a counterclaim); *Celgene Corp. v. Cipla Ltd.*, No. 2-19-cv-14731 (D.N.J. Jul. 3, 2019) (Cipla Ltd.) (also filed a counterclaim); *Cubist Pharms. LLC f/k/a Cubist Pharms., Inc. v. Cipla USA, Inc. et al.*, No. 3-19-cv-12920 (May 24, 2019) (Cipla Ltd.) (also filed a counterclaim).

**ANSWER:** Admitted.

## THE PATENTS-IN-SUIT

### The ’451 Patent

136. The ’451 patent, titled “Crystalline Freebase Forms of a Biphenyl Compound,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on September 24, 2013. A true and correct copy of the ’451 patent is attached as Exhibit A.

**ANSWER:** Cipla admits that Exhibit A to the First Amended Consolidated Complaint purports to be a copy of the ’451 patent. Cipla admits that the ’451 patent is entitled “Crystalline Freebase Forms of a Biphenyl Compound” and lists September 24, 2013 as an issue date. Cipla denies the remaining allegations in Paragraph 136.

137. Theravance Biopharma R&D IP, LLC is the assignee of the ’451 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the ’451 patent. Mylan Ireland Limited is the exclusive sub-licensee of the ’451 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee of the ’451 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 137 of the First Amended Consolidated Complaint, and therefore denies them.

138. The ’451 patent is listed in the Orange Book as covering YUPELRI®.

**ANSWER:** Cipla admits that the ’451 patent is listed in connection with YUPELRI® in the FDA’s Orange Book. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 138 of the First Amended Consolidated Complaint, and therefore denies them.

**The ’028 Patent**

139. The ’028 patent, titled “Crystalline Freebase Forms of a Biphenyl Compound,” was duly and legally issued by the USPTO on September 19, 2017. A true and correct copy of the ’028 patent is attached as Exhibit B.

**ANSWER:** Cipla admits that Exhibit B to the First Amended Consolidated Complaint purports to be a copy of the ’028 patent. Cipla admits that the ’028 patent is entitled “Crystalline Freebase Forms of a Biphenyl Compound” and lists September 19, 2017 as an issue date. Cipla denies the remaining allegations in Paragraph 139.

140. Theravance Biopharma R&D IP, LLC is the assignee of the ’028 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the ’028 patent. Mylan Ireland Limited is the exclusive sub-licensee of the ’028 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee on the face of the ’028 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 140 of the First Amended Consolidated Complaint, and therefore denies them.

141. The ’028 patent is listed in the Orange Book as covering YUPELRI®.

**ANSWER:** Cipla admits that the ’028 patent is listed in connection with YUPELRI® in the FDA’s Orange Book. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 141 of the First Amended Consolidated Complaint, and therefore denies them.

**The ’081 Patent**

142. The ’081 patent, titled “Crystalline Freebase Forms of a Biphenyl Compound,” was duly and legally issued by the USPTO on February 4, 2020. A true and correct copy of the ’081 patent is attached as Exhibit C.

**ANSWER:** Cipla admits that Exhibit C of the First Amended Consolidated Complaint purports to be a copy of the ’081 patent. Cipla admits that the ’081 patent is entitled “Crystalline Freebase Forms of a Biphenyl Compound” and lists February 4, 2020 as an issue date. Cipla denies the remaining allegations in Paragraph 142.

143. Theravance Biopharma R&D IP, LLC is the assignee of the ’081 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the ’081 patent. Mylan Ireland Limited is the exclusive sub-licensee of the ’081 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee on the face of the ’081 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 143 of the First Amended Consolidated Complaint, and therefore denies them.

144. The ’081 patent is listed in the Orange Book as covering YUPELRI®.

**ANSWER:** Cipla admits that the ’081 patent is listed in connection with YUPELRI® in the FDA’s Orange Book. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 144 of the First Amended Consolidated Complaint, and therefore denies them.

**The ’289 Patent**

145. The ’289 patent, titled “Crystalline Freebase Forms of a Biphenyl Compound,” was duly and legally issued by the USPTO on May 18, 2021. A true and correct copy of the ’289 patent is attached as Exhibit D.

**ANSWER:** Cipla admits that Exhibit D to the First Amended Consolidated Complaint purports to be a copy of the ’289 patent. Cipla admits that the ’289 patent is entitled “Crystalline

Freebase Forms of a Biphenyl Compound" and lists May 18, 2021 as an issue date. Cipla denies the remaining allegations in Paragraph 145.

146. Theravance Biopharma R&D IP, LLC is the assignee of the '289 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '289 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '289 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee on the face of the '289 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 146 of the First Amended Consolidated Complaint, and therefore denies them.

147. The '289 patent is listed in the Orange Book as covering YUPELRI® and its approved uses.

**ANSWER:** Cipla admits that the '289 patent is listed in connection with YUPELRI® in the FDA's Orange Book. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 147 of the First Amended Consolidated Complaint, and therefore denies them.

**The '531 Patent**

148. The '531 patent titled "Methods for Treating Chronic Obstructive Pulmonary Disease," was duly and legally issued by the USPTO on November 1, 2022. A true and correct copy of the '531 patent is attached as Exhibit E.

**ANSWER:** Cipla admits that Exhibit E to the First Amended Consolidated Complaint purports to be a copy of the '531 patent. Cipla admits that the '531 patent is entitled "Methods for Treating Chronic Obstructive Pulmonary Disease" and lists November 1, 2022 as an issue date. Cipla denies the remaining allegations in Paragraph 148.

149. Theravance Biopharma R&D IP, LLC is the assignee of the '531 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '531 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '531 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee on the face of the '531 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 149 of the First Amended Consolidated Complaint, and therefore denies them.

150. The '531 patent is listed in the Orange Book as covering YUPELRI® and its approved uses.

**ANSWER:** Cipla admits that the '531 patent is listed in connection with YUPELRI® in the FDA's Orange Book. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 150 of the First Amended Consolidated Complaint, and therefore denies them.

**The '948 Patent**

151. The '948 patent, titled "Crystalline Freebase Forms of a Biphenyl Compound," was duly and legally issued by the USPTO on July 4, 2023. A true and correct copy of the '948 patent is attached as Exhibit G.

**ANSWER:** Cipla admits that Exhibit A to the First Amended Consolidated Complaint purports to be a copy of the '948 patent. Cipla admits that the '948 patent is entitled "Crystalline Freebase Forms of a Biphenyl Compound" and lists July 4, 2023 as an issue date. Cipla denies the remaining allegations in Paragraph 151.

152. Theravance Biopharma R&D IP, LLC is the assignee of the '948 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '948 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '948 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee of the '948 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 152 of the First Amended Consolidated Complaint, and therefore denies them.

153. The ’948 patent is listed in the Orange Book as covering YUPELRI® and its approved uses.

**ANSWER:** Cipla admits that the ’948 patent is listed in connection with YUPELRI® in the FDA’s Orange Book. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 153 of the First Amended Consolidated Complaint, and therefore denies them.

**The ’783 Patent**

154. The ’783 patent titled “Biphenyl Compounds Useful as Muscarinic Receptor Antagonists,” was duly and legally issued by the USPTO on September 13, 2011. A true and correct copy of the ’783 patent is attached as Exhibit H.

**ANSWER:** Cipla admits that Exhibit H to the First Amended Consolidated Complaint purports to be a copy of the ’783 patent. Cipla admits that the ’783 patent is entitled “Biphenyl Compounds Useful as Muscarinic Receptor Antagonists” and lists September 13, 2011 as an issue date. Cipla denies the remaining allegations in Paragraph 154.

155. Theravance Biopharma R&D IP, LLC is the assignee of the ’783 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the ’783 patent. Mylan Ireland Limited is the exclusive sub-licensee of the ’783 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee of the ’783 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 155 and therefore denies them.

**The ’099 Patent**

156. The ’099 patent titled “Crystalline Forms of a Biphenyl Compound,” was duly and legally issued by the USPTO on February 2, 2016. A true and correct copy of the ’099 patent is attached as Exhibit I.

**ANSWER:** Cipla admits that Exhibit I to the First Amended Consolidated Complaint purports to be a copy of the ’099 patent. Cipla admits that the ’099 patent is entitled “Crystalline

Freebase Forms of a Biphenyl Compound" and lists February 2, 2016 as an issue date. Cipla denies the remaining allegations in Paragraph 156.

157. Theravance Biopharma R&D IP, LLC is the assignee of the '099 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '099 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '099 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee of the '099 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 157 of the First Amended Consolidated Complaint, and therefore denies them.

**The '013 Patent**

158. The '013 patent titled "Crystalline Freebase Forms of a Biphenyl Compound," was duly and legally issued by the USPTO on October 16, 2018. A true and correct copy of the '013 patent is attached as Exhibit J.

**ANSWER:** Cipla admits that Exhibit J to the First Amended Consolidated Complaint purports to be a copy of the '013 patent. Cipla admits that the '013 patent is entitled "Crystalline Freebase Forms of a Biphenyl Compound" and lists October 16, 2018 as an issue date. Cipla denies the remaining allegations in Paragraph 158.

159. Theravance Biopharma R&D IP, LLC is the assignee of the '013 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '013 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '013 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee of the '013 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 159 of the First Amended Consolidated Complaint, and therefore denies them.

**The '209 Patent**

160. The ’209 patent titled “Crystalline Freebase Forms of a Biphenyl Compound,” was duly and legally issued by the USPTO on May 16, 2023. A true and correct copy of the ’209 patent is attached as Exhibit K.

**ANSWER:** Cipla admits that Exhibit K to the First Amended Consolidated Complaint purports to be a copy of the ’209 patent. Cipla admits that the ’209 patent is entitled “Crystalline Freebase Forms of a Biphenyl Compound” and lists May 16, 2023 as an issue date. Cipla denies the remaining allegations in Paragraph 160.

161. Theravance Biopharma R&D IP, LLC is the assignee of the ’209 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the ’209 patent. Mylan Ireland Limited is the exclusive sub-licensee of the ’209 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed on the face of the ’209 patent as the assignee, but is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 161 of the First Amended Consolidated Complaint, and therefore denies them because it does not appear that any assignment has been recorded for the ’209 patent.

## THE COLSON PATENTS-IN-SUIT

### The ’225 Patent

162. The ’225 patent titled “Process for Preparing a Biphenyl-2-ylcarbamic Acid,” was duly and legally issued by the USPTO on June 17, 2014. A true and correct copy of the ’225 patent is attached as Exhibit L.

**ANSWER:** Cipla admits that Exhibit L to the First Amended Consolidated Complaint purports to be a copy of the ’225 patent. Cipla admits that the ’225 patent is entitled “Process for Preparing a Biphenyl-2-ylcarbamic Acid” and lists June 17, 2014 as an issue date. Cipla denies the remaining allegations in Paragraph 162.

163. Theravance Biopharma R&D IP, LLC is the assignee of the ’225 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the ’225 patent. Mylan Ireland Limited is the exclusive sub-licensee of the ’225 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee of the '225 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 163 of the First Amended Consolidated Complaint, and therefore denies them.

**The '061 Patent**

164. The '061 patent titled "Process for Preparing a Biphenyl-2-ylcarbamic Acid," was duly and legally issued by the USPTO on May 19, 2015. A true and correct copy of the '061 patent is attached as Exhibit M.

**ANSWER:** Cipla admits that Exhibit M to the First Amended Consolidated Complaint purports to be a copy of the '061 patent. Cipla admits that the '061 patent is entitled "Process for Preparing a Biphenyl-2-ylcarbamic Acid" and lists May 19, 2015 as an issue date. Cipla denies the remaining allegations in Paragraph 164.

165. Theravance Biopharma R&D IP, LLC is the assignee of the '061 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '061 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '061 patent from Theravance Biopharma Ireland Limited.

**ANSWER:** Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee of the '061 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 165 of the First Amended Consolidated Complaint, and therefore denies them.

**YUPELRI®**

166. Plaintiffs are engaged in the business of creating, developing, and bringing to market innovative pharmaceutical products for the treatment of diseases.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 166 of the First Amended Consolidated Complaint, and therefore denies them.

167. Plaintiffs' YUPELRI® (revefenacin) is a prescription medicine indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD"), a chronic inflammatory lung disease characterized by progressive persistent airflow obstruction. Revefenacin is a long-acting muscarinic antagonist, which is often referred to as an anticholinergic. It is administered long-term as one vial of YUPELRI®, one time each day, by the orally inhaled route via a jet nebulizer.

**ANSWER:** Cipla admits that the YUPELRI® label recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)," and that "[r]evefenacin is a long-acting muscarinic antagonist, which is often referred to as an anticholinergic." Cipla further admits that the label states "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 167 of the First Amended Consolidated Complaint, and therefore denies them.

168. FDA regulations require that approved drug products include prescribing information reciting the FDA-approved indication(s) for the drug and related instructions for healthcare providers to safely and effectively administer the drug. *See* 21 C.F.R. § 201.56(a)(1)¬(3), (d)(1); 21 C.F.R. § 201.57(a)-(c).

**ANSWER:** Paragraph 168 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 168.

169. Consistent with FDA regulations, the package insert for YUPELRI® includes prescribing information that recites the FDA-approved indication for YUPELRI® and provides instructions for healthcare providers and patients to safely and effectively administer YUPELRI®.

**ANSWER:** Paragraph 169 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 169.

170. Attached as Exhibit F is a true and correct copy of the May 2022 YUPELRI® package insert, which is the current version of the YUPELRI® package insert.

**ANSWER:** Cipla admits that Exhibit F to the First Amended Consolidated Complaint purports to be a copy of the May 2022 YUPELRI® package insert. Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 170 of the First Amended Consolidated Complaint, and therefore denies them.

171. YUPELRI® is indicated for the maintenance treatment of patients with COPD. (Ex. F at § 1).

**ANSWER:** Cipla admits that the YUPELRI® label recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." The remainder of Paragraph 171 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the remaining allegations of Paragraph 171.

172. YUPELRI® was studied in two 12-week replicate placebo-controlled trials in patients with moderate to very severe COPD. The population had COPD with a mean post-bronchodilator forced expiratory volume in one second (FEV1) percent predicted of 55% (range: 10% to 90%). (Ex. F at § 14.2).

**ANSWER:** Cipla admits that the YUPELRI® label recites "[t]he clinical development program for YUPELRI included two 12-week, randomized, doubleblind, placebo-controlled, multiple-dose, parallel-group, confirmatory trials in subjects with moderate to very severe COPD." The label also states "[a]t screening, the mean post-brochnodilator percent predicted FEV1 was 55% (range: 10% to 90%), and the post-bronchodilator FEV1/FVC ratio was 0.54 (range: 0.3 to 0.7)." The remainder of Paragraph 172 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the allegations of Paragraph 172.

**COPD**

173. COPD is a chronic inflammatory lung disease characterized by progressive persistent airflow obstruction. Bronchodilators, such as muscarinic receptor antagonists and β-adrenergic agonists, are used to treat COPD. Such bronchodilators are typically delivered to a patient in need of treatment using an inhalation delivery device, such as a dry powder inhaler, a metered dose inhaler or a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 173 of the First Amended Consolidated Complaint, and therefore denies them.

174. Healthcare providers use guidelines from the Global Initiative for Chronic Obstructive Lung Disease, commonly known as the GOLD guidelines, to determine treatment algorithms for COPD patients. The GOLD guidelines are regularly updated, most recently for 2023.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 174 of the First Amended Consolidated Complaint, and therefore denies them.

175. The GOLD guidelines grade COPD into mild, moderate, severe, and very severe classifications based on the severity of airflow obstruction. Airflow obstruction is measured as forced expiratory volume in one second (FEV1). According to the GOLD guidelines, severe includes patients with a percent predicted FEV1 of equal to or greater than 30% and less than 50%. According to the GOLD guidelines, very severe includes patients with a percent predicted FEV1 of less than 30%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 175 of the First Amended Consolidated Complaint, and therefore denies them.

176. The GOLD guidelines also call for healthcare providers to assess patients' ability to use an inhaler regularly. Inspiratory flow is recognized as an important factor in successfully using inhalers. The GOLD guidelines state that each dry powder inhaler has a unique internal resistance and patients must create turbulent energy within the device during inhalation to disaggregate the powder into fine particles. The GOLD guidelines continue by instructing healthcare providers to check visually that the patient can inhale forcefully through the device.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 176 of the First Amended Consolidated Complaint, and therefore denies them.

177. For many patients, any type of inhalation delivery device can be used to deliver an adequate dose of a bronchodilator. However, for COPD patients having a lower than normal inspiratory flow rate, nebulizers are sometimes recommended since these patients may be unable to generate a peak inspiratory flow rate ("PIFR") sufficient for proper use of a dry powder inhaler.

*See, e.g.*, Mahler, D.A., *Peak Inspiratory Flow Rate as a Criterion for Dry Powder Inhaler Use in Chronic Obstructive Pulmonary Disease*, 14(7) Ann. Am. Thorac. Soc. 1103-07 (Jul. 2017) ("Mahler 2017"); Mahler, D.A. et al., *Comparison of dry powder versus nebulized beta-agonist in patients with COPD who have suboptimal peak inspiratory flow rate*, 27(2) J. Aerosol Med. Pulm. Drug Deliv. 103-09 (Apr. 2014) ("Mahler 2014"). Accordingly, use of a nebulizer for delivery of a bronchodilator has been suggested for COPD patients having a low PIFR.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 177 of the First Amended Consolidated Complaint, and therefore denies them.

178. Low PIFR is also referred to as suboptimal PIFR. Low or suboptimal PIFR can be readily established, for example, using the IN-CHECK DIAL® device which can, for example, simulate the resistance of a dry powder inhaler such as the DISKUS® device.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 178 of the First Amended Consolidated Complaint, and therefore denies them.

179. If the PIFR value is less than about 60 L/min, the patient may not achieve optimal clinical benefit from a dry powder inhaler. A PIFR of less than 30 L/min is insufficient for a dry powder inhaler.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 179 of the First Amended Consolidated Complaint, and therefore denies them.

## ACTS GIVING RISE TO THIS ACTION

### Eugia

180. In a letter dated January 9, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Eugia Notice Letter"), Eugia notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted ANDA No. 218128 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of the Eugia ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent (collectively, the "Eugia Notice Letter Patents").

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 180 of the First Amended Consolidated Complaint, and therefore denies them.

181. On information and belief, Eugia included in the Eugia ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Eugia Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the Eugia Notice Letter Patents are invalid, unenforceable, and/or will not be infringed by the Eugia ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 181 of the First Amended Consolidated Complaint, and therefore denies them.

182. Eugia filed the Eugia Paragraph IV Certification without adequate justification for asserting that the Eugia Notice Letter Patents are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Eugia ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 182 of the First Amended Consolidated Complaint, and therefore denies them.

183. In the Notice Letter, Eugia offered confidential access to portions of its ANDA No. 218128, on terms and conditions set forth in the Eugia Notice Letter ("the Eugia Offer"). Eugia requested that Plaintiffs accept the Eugia Offer before receiving access to the Eugia ANDA. The Eugia Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 183 of the First Amended Consolidated Complaint, and therefore denies them.

184. Plaintiffs filed a complaint for infringement of the Eugia Notice Letter Patents against Eugia, *inter alia*, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement against, *inter alia*, Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma USA, Inc., and

Aurobindo Pharma Limited, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 184 of the First Amended Consolidated Complaint, and therefore denies them.

185. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

**ANSWER:** Cipla admits that the face of the '948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a "Submission Date" of July 5, 2023 for the '948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 185.

186. In a letter dated July 31, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Eugia Second Notice Letter"), Eugia notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that the Eugia ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Eugia '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Eugia ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 186 of the First Amended Consolidated Complaint, and therefore denies them.

187. The Eugia Second Notice Letter states that "in Eugia's opinion and to the best of its knowledge, the ['948] patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Eugia's ANDA." (Eugia Second Notice Letter at 3).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 187 of the First Amended Consolidated Complaint, and therefore denies them.

188. Eugia filed the Eugia '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or not infringed by the

commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Eugia ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 188 of the First Amended Consolidated Complaint, and therefore denies them.

189. Eugia also attached to the Eugia Second Notice Letter a "Detailed Factual and Legal Basis for Eugia's Paragraph IV Certification Regarding [the '948 patent]."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 189 of the First Amended Consolidated Complaint, and therefore denies them.

190. The Eugia Second Notice Letter does not provide a substantive unenforceability defense to the '948 patent in the "Detailed Factual and Legal Basis."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 190 of the First Amended Consolidated Complaint, and therefore denies them.

191. Plaintiffs filed a complaint for infringement of the '948 patent against Eugia, *inter alia*, in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125.)

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement of the '948 patent against, *inter alia*, Eugia Pharma Specialities Ltd. ("Eugia Pharma"), Eugia US LLC ("Eugia US"), Aurobindo Pharma USA, Inc. ("Aurobindo USA"), Aurobindo Pharma Limited ("Aurobindo Ltd.") (collectively, "Eugia"), in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125). Cipla denies the remaining allegations of paragraph 191.

192. On information and belief, the active ingredient of the Eugia ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions, methods of use, and processes described and claimed in one or more claims of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 192 of the First Amended Consolidated Complaint, and therefore denies them.

193. On information and belief, Eugia asserts in ANDA No. 218128 that the Eugia ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Eugia, demonstrate the bioequivalence of the Eugia ANDA Product to YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 193 of the First Amended Consolidated Complaint, and therefore denies them.

194. On information and belief, Eugia is seeking approval to market the Eugia ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 194 of the First Amended Consolidated Complaint, and therefore denies them.

195. On information and belief, Eugia is seeking approval to market the Eugia ANDA Product for maintenance treatment of patients with COPD.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 195 of the First Amended Consolidated Complaint, and therefore denies them.

196. On information and belief, Eugia had knowledge of the Eugia Notice Letter Patents when it submitted and filed ANDA No. 218128.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 196 of the First Amended Consolidated Complaint, and therefore denies them.

197. On information and belief, Eugia had knowledge of the ’948 patent when it submitted and filed the Eugia ’948 Patent Paragraph IV Certification to ANDA No. 218128.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 197 of the First Amended Consolidated Complaint, and therefore denies them.

198. On information and belief, Eugia has actual knowledge as of the date of this First Amended Complaint of the Patents-in-Suit, at least because Plaintiffs have identified all of the Patents-in-Suit to Eugia as part of this Action.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 198 of the First Amended Consolidated Complaint, and therefore denies them.

199. On information and belief, Eugia intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the Patents-in-Suit upon receiving FDA approval of ANDA No. 218128 and prior to the expiration of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 199 of the First Amended Consolidated Complaint, and therefore denies them.

200. On information and belief, Eugia will commercially manufacture, use, offer for sale, and/or sell the Eugia ANDA Product throughout the United States, import the Eugia ANDA Product into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 200 of the First Amended Consolidated Complaint, and therefore denies them.

201. On information and belief, Eugia knows that the Eugia ANDA Product is especially made or adapted for use in a way that would infringe the Patents-in-Suit, and is not suitable for substantial non-infringing use. On information and belief, Eugia knowingly has taken and intends to take active steps to, and will, induce and/or contribute to infringement of one or more claims of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 201 of the First Amended Consolidated Complaint, and therefore denies them.

202. On information and belief, Eugia uses processes covered by one or more claims of the Patents-in-Suit to prepare the Eugia ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 202 of the First Amended Consolidated Complaint, and therefore denies them.

203. On information and belief, the Eugia ANDA Product resulting from the processes claimed in one or more Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 203 of the First Amended Consolidated Complaint, and therefore denies them.

204. The Eugia ANDA Product resulting from the processes claimed by one or more Patents-in-Suit is not a nonessential and/or trivial component of another product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 204 of the First Amended Consolidated Complaint, and therefore denies them.

205. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Eugia with respect to infringement of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 205 of the First Amended Consolidated Complaint, and therefore denies them.

206. This action was commenced within 45 days of receipt of the Eugia Notice Letter.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 206 of the First Amended Consolidated Complaint, and therefore denies them.

**Mankind**

207. In a letter dated January 5, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Mankind Notice Letter"), Mankind notified Mylan Ireland Limited that it had submitted ANDA No. 218089 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of the Mankind ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent (collectively, the "Mankind Notice Letter Patents").

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 207 of the First Amended Consolidated Complaint, and therefore denies them.

208. On information and belief, Mankind included in the Mankind ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Mankind Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the Mankind Notice Letter Patents are invalid, unenforceable, and/or will not be infringed by the Mankind ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 208 of the First Amended Consolidated Complaint, and therefore denies them.

209. Mankind filed the Mankind Paragraph IV Certification without adequate justification for asserting that the Mankind Notice Letter Patents are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Mankind ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 209 of the First Amended Consolidated Complaint, and therefore denies them.

210. The Mankind Notice Letter states that Mankind has attached a "detailed statement of the factual and legal bases for Mankind's Paragraph IV certifications that, in its opinion, the [Patents-in-Suit] are invalid and/or not infringed by Mankind's revefenacin inhalation solution

vials (175 mcg / 3 ml).” Mankind Notice Letter at 2. Neither the Mankind Notice Letter nor its attached “detailed statement” provide any substantive invalidity allegation with respect to the ’451 patent, ’028 patent, ’081 patent, and ’289 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 210 of the First Amended Consolidated Complaint, and therefore denies them.

211. In the Notice Letter, Mankind offered confidential access to portions of its ANDA No. 218089, on terms and conditions set forth in the Mankind Notice Letter (“the Mankind Offer”). Mankind requested that Plaintiffs accept the Mankind Offer before receiving access to the Mankind ANDA. The Mankind Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 211 of the First Amended Consolidated Complaint, and therefore denies them.

212. Plaintiffs filed a complaint for infringement of the Mankind Notice Letter Patents against Mankind, *inter alia*, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement against, *inter alia*¸ Mankind Pharma Ltd. (“Mankind Pharma”), Lifestar Pharma LLC (“Lifestar”) (collectively, “Mankind”), in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 212 of the First Amended Consolidated Complaint, and therefore denies them.

213. On July 4, 2023, the ’948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

**ANSWER:** Cipla admits that the face of the ’948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a “Submission Date” of July 5, 2023

for the '948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 213.

214. In a letter dated July 10, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Mankind Second Notice Letter"), Mankind notified Mylan Ireland Limited and Theravance Biopharma US, Inc. that the Mankind ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Mankind '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Mankind ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 214 of the First Amended Consolidated Complaint, and therefore denies them.

215. The Mankind Second Notice Letter states that "in its opinion, the '948 patent is invalid and/or not infringed by" the Mankind ANDA Product. (Mankind Second Notice Letter at 2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 215 of the First Amended Consolidated Complaint, and therefore denies them.

216. Mankind filed the Mankind '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Mankind ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 216 of the First Amended Consolidated Complaint, and therefore denies them.

217. Mankind also attached to the Mankind Second Notice Letter a "Detailed Statement of the Factual and Legal Basis for its Opinion that U.S. Patent No. 11,691,948 is invalid, unenforceable and/or will not be infringed by Mankind's manufacture, use, offer for sale, or sale of Mankind's Revefenacin inhalation solution vials (175 mcg / 3 mL)."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 217 of the First Amended Consolidated Complaint, and therefore denies them.

218. The Mankind Second Notice Letter does not provide a substantive unenforceability defense to the '948 patent in the "Detailed Statement."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 217 of the First Amended Consolidated Complaint, and therefore denies them.

219. Plaintiffs filed a complaint for infringement of the '948 patent against Mankind, *inter alia*, in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125.)

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement of the '948 patent against, *inter alia*¸ Mankind Pharma Ltd. ("Mankind Pharma"), Lifestar Pharma LLC ("Lifestar") (collectively, "Mankind"), in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125). Cipla denies the remaining allegations of paragraph 219.

220. On information and belief, the active ingredient of the Mankind ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions, methods of use, and processes described and claimed in one or more claims of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 220 of the First Amended Consolidated Complaint, and therefore denies them

221. On information and belief, Mankind asserts in ANDA No. 218089 that the Mankind ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Mankind, demonstrate the bioequivalence of the Mankind ANDA Product to YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 221 of the First Amended Consolidated Complaint, and therefore denies them

222. On information and belief, Mankind is seeking approval to market the Mankind ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 222 of the First Amended Consolidated Complaint, and therefore denies them

223. On information and belief, Mankind is seeking approval to market the Mankind ANDA Product for maintenance treatment of patients with COPD.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 223 of the First Amended Consolidated Complaint, and therefore denies them

224. On information and belief, Mankind had knowledge of the Mankind Notice Letter Patents when it submitted and filed ANDA No. 218089.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 224 of the First Amended Consolidated Complaint, and therefore denies them

225. On information and belief, Mankind had knowledge of the ’948 patent when it submitted and filed the Mankind ’948 Patent Paragraph IV Certification to ANDA No. 218089.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 225 of the First Amended Consolidated Complaint, and therefore denies them

226. On information and belief, Mankind has actual knowledge as of the date of this First Amended Complaint of the Patents-in-Suit, at least because Plaintiffs have identified all of the Patents-in-Suit to Mankind as part of this Action.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 226 of the First Amended Consolidated Complaint, and therefore denies them.

227. On information and belief, Mankind intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the Patents-in-Suit upon receiving FDA approval of ANDA No. 218089 and prior to the expiration of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 227 of the First Amended Consolidated Complaint, and therefore denies them.

228. On information and belief, Mankind will commercially manufacture, use, offer for sale, and/or sell the Mankind ANDA Product throughout the United States, import the Mankind ANDA Product into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 228 of the First Amended Consolidated Complaint, and therefore denies them.

229. On information and belief, Mankind knows that the Mankind ANDA Product is especially made or adapted for use in a way that would infringe the Patents-in-Suit, and is not suitable for substantial non-infringing use. On information and belief, Mankind knowingly has taken and intends to take active steps to, and will, induce and/or contribute to infringement of one or more claims of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 229 of the First Amended Consolidated Complaint, and therefore denies them.

230. On information and belief, Mankind uses processes covered by one or more claims of the Patents-in-Suit to prepare the Mankind ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 230 of the First Amended Consolidated Complaint, and therefore denies them.

231. On information and belief, the Mankind ANDA Product resulting from the processes claimed in one or more Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 231 of the First Amended Consolidated Complaint, and therefore denies them.

232. The Mankind ANDA Product resulting from the processes claimed by one or more Patents-in-Suit is not a nonessential and/or trivial component of another product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 232 of the First Amended Consolidated Complaint, and therefore denies them.

233. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Mankind with respect to infringement of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 233 of the First Amended Consolidated Complaint, and therefore denies them.

234. This action was commenced within 45 days of receipt of the Mankind Notice Letter.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 234 of the First Amended Consolidated Complaint, and therefore denies them.

**Accord**

235. In a letter dated January 6, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Accord Notice Letter"), Accord notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted ANDA No. 218100 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of the Accord ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent (collectively, the "Accord Notice Letter Patents").

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 235 of the First Amended Consolidated Complaint, and therefore denies them.

236. On information and belief, Accord included in the Accord ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Accord Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the Accord Notice Letter Patents are invalid, unenforceable, and/or will not be infringed by the Accord ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 236 of the First Amended Consolidated Complaint, and therefore denies them.

237. Accord filed the Accord Paragraph IV Certification without adequate justification for asserting that the Accord Notice Letter Patents are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Accord ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 237 of the First Amended Consolidated Complaint, and therefore denies them.

238. The Accord Notice Letter states that Accord has attached a "detailed statement of the factual and legal basis of Accord's opinion that U.S. Patent Nos. 8541451, 976028, 10550081, 11008289, and 11484531 are invalid, unenforceable, and/or will not be infringed." Accord Notice Letter at 2. Neither the Accord Notice Letter nor its attached "detailed statement" provide any substantive invalidity allegation with respect to the '451 patent, '028 patent, '081 patent, and '289 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 238 of the First Amended Consolidated Complaint, and therefore denies them.

239. In the Notice Letter, Accord offered confidential access to portions of its ANDA No. 218100, on terms and conditions set forth in the Accord Notice Letter ("the Accord Offer"). Accord requested that Plaintiffs accept the Accord Offer before receiving access to the Accord ANDA. The Accord Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 239 of the First Amended Consolidated Complaint, and therefore denies them.

240. Plaintiffs filed a complaint for infringement of the Accord Notice Letter Patents against Accord, *inter alia*, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement against, *inter alia*, Accord Healthcare, Inc. ("Accord Inc."), Accord Healthcare, Ltd. ("Accord Ltd."), Intas Pharmaceuticals Ltd. ("Intas") (collectively, "Accord"), in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 240 of the First Amended Consolidated Complaint, and therefore denies them.

241. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

**ANSWER:** Cipla admits that the face of the '948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a "Submission Date" of July 5, 2023 for the '948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 241.

242. In a letter dated July 19, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Accord Second Notice Letter"), Accord notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that the Accord ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Accord '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Accord ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 242 of the First Amended Consolidated Complaint, and therefore denies them.

243. The Accord Second Notice Letter states that, in its opinion, the '948 patent is "invalid, unenforceable, and/or will not be infringed" by the Accord ANDA Product. (Accord Second Notice Letter at 1.)

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 243 of the First Amended Consolidated Complaint, and therefore denies them.

244. Accord filed the Accord '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Accord ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 244 of the First Amended Consolidated Complaint, and therefore denies them.

245. Accord also attached a "detailed statement of the factual and legal basis of Accord's opinion that U.S. Patent No. 11691948 is invalid, unenforceable, and/or will not be infringed."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 245 of the First Amended Consolidated Complaint, and therefore denies them.

246. The Accord Second Notice Letter does not provide a substantive invalidity and unenforceability defense to the '948 patent in the "Detailed Statement."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 246 of the First Amended Consolidated Complaint, and therefore denies them.

247. Plaintiffs filed a complaint for infringement of the '948 patent against Accord, *inter alia*, in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125.)

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement of the '948 patent against, *inter alia*, Accord Healthcare, Inc. ("Accord Inc."), Accord Healthcare, Ltd. ("Accord Ltd."), in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125). Cipla denies the remaining allegations of paragraph 247.

248. On information and belief, the active ingredient of the Accord ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions, methods of use, and processes described and claimed in one or more claims of the Patents-in-Suit and the Colson Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 248 of the First Amended Consolidated Complaint, and therefore denies them.

249. On information and belief, Accord asserts in ANDA No. 218100 that the Accord ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Accord, demonstrate the bioequivalence of the Accord ANDA Product to YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 249 of the First Amended Consolidated Complaint, and therefore denies them.

250. On information and belief, Accord is seeking approval to market the Accord ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 250 of the First Amended Consolidated Complaint, and therefore denies them.

251. On information and belief, Accord is seeking approval to market the Accord ANDA Product for maintenance treatment of patients with COPD.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 251 of the First Amended Consolidated Complaint, and therefore denies them.

252. On information and belief, Accord had knowledge of the Accord Notice Letter Patents when it submitted and filed ANDA No. 218100.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 252 of the First Amended Consolidated Complaint, and therefore denies them.

253. On information and belief, Accord had knowledge of the '948 patent when it submitted and filed the Accord '948 Patent Paragraph IV Certification to ANDA No. 218100.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 253 of the First Amended Consolidated Complaint, and therefore denies them.

254. On information and belief, Accord has actual knowledge as of the date of this First Amended Complaint of the Patents-in-Suit and the Colson Patents-in-Suit, at least because Plaintiffs have identified all of the Patents-in-Suit and the Colson Patents-in-Suit to Accord as part of this Action.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 254 of the First Amended Consolidated Complaint, and therefore denies them.

255. On information and belief, Accord intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the Patents-in-Suit and the Colson Patents-in-Suit upon receiving FDA approval of ANDA No. 218100 and prior to the expiration of the Patents-in-Suit and the Colson Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 255 of the First Amended Consolidated Complaint, and therefore denies them.

256. On information and belief, Accord will commercially manufacture, use, offer for sale, and/or sell the Accord ANDA Product throughout the United States, import the Accord ANDA Product into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the terms of the Patents-in-Suit and the Colson Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 256 of the First Amended Consolidated Complaint, and therefore denies them.

257. On information and belief, Accord knows that the Accord ANDA Product is especially made or adapted for use in a way that would infringe the Patents-in-Suit and the Colson Patents-in-Suit, and is not suitable for substantial non-infringing use. On information and belief, Accord knowingly has taken and intends to take active steps to, and will, induce and/or contribute to infringement of one or more claims of the Patents-in-Suit and the Colson Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 257 of the First Amended Consolidated Complaint, and therefore denies them.

258. On information and belief, Accord uses processes covered by one or more claims of the Patents-in-Suit and the Colson Patents-in-Suit to prepare the Accord ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 258 of the First Amended Consolidated Complaint, and therefore denies them.

259. On information and belief, the Accord ANDA Product resulting from the processes claimed in one or more Patents-in-Suit and/or Colson Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more Patents-in-Suit and/or Colson Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 259 of the First Amended Consolidated Complaint, and therefore denies them.

260. The Accord ANDA Product resulting from the processes claimed by one or more Patents-in-Suit and/or Colson Patents-in-Suit is not a nonessential and/or trivial component of another product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 260 of the First Amended Consolidated Complaint, and therefore denies them.

261. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Accord with respect to infringement of the Patents-in-Suit and the Colson Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 261 of the First Amended Consolidated Complaint, and therefore denies them.

262. This action was commenced within 45 days of receipt of the Accord Notice Letter.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 262 of the First Amended Consolidated Complaint, and therefore denies them.

**Medichem**

263 - 310. *[REDACTED IN SERVICE COPY TO CIPLA]*

**ANSWER:** Because Paragraphs 263-310 were sealed and redacted from the service copy of the First Amended Consolidated Complaint which Cipla received, Cipla deems that no answer to those paragraphs is necessary. To the extent such answer is required, Cipla denies Paragraphs 263-310.

**Lupin**

311. In a letter dated January 5, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Lupin Notice Letter"), Lupin notified Mylan Ireland Limited and Theravance Biopharma R&D IP LLC that it had submitted ANDA No. 218088 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of the Lupin ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent (collectively, the "Lupin Notice Letter Patents").

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 311 of the First Amended Consolidated Complaint, and therefore denies them.

312. On information and belief, Lupin included in the Lupin ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Lupin Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the Lupin Notice Letter Patents are invalid, unenforceable, and/or will not be infringed by the Lupin ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 312 of the First Amended Consolidated Complaint, and therefore denies them.

313. Lupin filed the Lupin Paragraph IV Certification without adequate justification for asserting that the Lupin Notice Letter Patents are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Lupin ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 313 of the First Amended Consolidated Complaint, and therefore denies them.

314. In the Notice Letter, Lupin offered confidential access to portions of its ANDA No. 218088, on terms and conditions set forth in the Lupin Notice Letter ("the Lupin Offer"). Lupin requested that Plaintiffs accept the Lupin Offer before receiving access to the Lupin ANDA. The Lupin Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 314 of the First Amended Consolidated Complaint, and therefore denies them.

315. Plaintiffs filed a complaint for infringement of the Lupin Notice Letter Patents against Lupin, *inter alia*, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement against, *inter alia*, Lupin Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (collectively,

"Lupin"), in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 315 of the First Amended Consolidated Complaint, and therefore denies them.

316. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

**ANSWER:** Cipla admits that the face of the '948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a "Submission Date" of July 5, 2023 for the '948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 316.

317. In a letter dated August 3, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Lupin Second Notice Letter"), Lupin notified Mylan Ireland Limited, Mylan Pharmaceuticals Inc., Theravance Biopharma R&D IP LLC, and Theravance Biopharma Ireland Ltd. that the Lupin ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Lupin '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Lupin ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 317 of the First Amended Consolidated Complaint, and therefore denies them.

318. The Lupin Second Notice Letter states that "in its opinion and to the best of its knowledge, each claim of the '948 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Lupin's ANDA." (Lupin Second Notice Letter at 2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 318 of the First Amended Consolidated Complaint, and therefore denies them.

319. Lupin filed the Lupin '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or not infringed by the

commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Lupin ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 319 of the First Amended Consolidated Complaint, and therefore denies them.

320. Lupin also attached to the Lupin Second Notice Letter a "Detailed Statement of the Factual and Legal Bases for Lupin's ANDA Certification That the Claims of U.S. Patent No. 11,691,948 Will Not Be Infringed, Are Invalid, and/or Are Unenforceable."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 320 of the First Amended Consolidated Complaint, and therefore denies them.

321. The Lupin Second Notice Letter does not provide a substantive unenforceability defense to the '948 patent in the "Detailed Statement."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 321 of the First Amended Consolidated Complaint, and therefore denies them.

322. Plaintiffs filed a complaint for infringement of the '948 patent against Lupin, *inter alia*, in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125.)

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement of the '948 patent against, *inter alia*, Lupin Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (collectively, "Lupin"), in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125). Cipla denies the remaining allegations of paragraph 322.

323. On information and belief, the active ingredient of the Lupin ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions, methods of use, and processes described and claimed in one or more claims of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 323 of the First Amended Consolidated Complaint, and therefore denies them.

324. On information and belief, Lupin asserts in ANDA No. 218088 that the Lupin ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Lupin, demonstrate the bioequivalence of the Lupin ANDA Product to YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 324 of the First Amended Consolidated Complaint, and therefore denies them.

325. On information and belief, Lupin is seeking approval to market the Lupin ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 325 of the First Amended Consolidated Complaint, and therefore denies them.

326. On information and belief, Lupin is seeking approval to market the Lupin ANDA Product for maintenance treatment of patients with COPD.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 326 of the First Amended Consolidated Complaint, and therefore denies them.

327. On information and belief, Lupin had knowledge of the Lupin Notice Letter Patents when it submitted and filed ANDA No. 218088.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 327 of the First Amended Consolidated Complaint, and therefore denies them.

328. On information and belief, Lupin had knowledge of the ’948 patent when it submitted and filed the Lupin ’948 Patent Paragraph IV Certification to ANDA No. 218088.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 328 of the First Amended Consolidated Complaint, and therefore denies them.

329. On information and belief, Lupin has actual knowledge as of the date of this First Amended Complaint of the Patents-in-Suit, at least because Plaintiffs have identified all of the Patents-in-Suit to Lupin as part of this Action.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 329 of the First Amended Consolidated Complaint, and therefore denies them.

330. On information and belief, Lupin intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the Patents-in-Suit upon receiving FDA approval of ANDA No. 218088 and prior to the expiration of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 330 of the First Amended Consolidated Complaint, and therefore denies them.

331. On information and belief, Lupin will commercially manufacture, use, offer for sale, and/or sell the Lupin ANDA Product throughout the United States, import the Lupin ANDA Product into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 331 of the First Amended Consolidated Complaint, and therefore denies them.

332. On information and belief, Lupin knows that the Lupin ANDA Product is especially made or adapted for use in a way that would infringe the Patents-in-Suit, and is not suitable for substantial non-infringing use. On information and belief, Lupin knowingly has taken and intends to take active steps to, and will, induce and/or contribute to infringement of one or more claims of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 332 of the First Amended Consolidated Complaint, and therefore denies them.

333. On information and belief, Lupin uses processes covered by one or more claims of the Patents-in-Suit to prepare the Lupin ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 333 of the First Amended Consolidated Complaint, and therefore denies them.

334. On information and belief, the Lupin ANDA Product resulting from the processes claimed in one or more Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 334 of the First Amended Consolidated Complaint, and therefore denies them.

335. The Lupin ANDA Product resulting from the processes claimed by one or more Patents-in-Suit is not a nonessential and/or trivial component of another product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 335 of the First Amended Consolidated Complaint, and therefore denies them.

336. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Lupin with respect to infringement of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 336 of the First Amended Consolidated Complaint, and therefore denies them.

337. This action was commenced within 45 days of receipt of the Lupin Notice Letter.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 337 of the First Amended Consolidated Complaint, and therefore denies them.

**Orbicular**

338. In a letter dated January 13, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Orbicular Notice Letter"), Orbicular notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted ANDA No. 217868 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of the Orbicular ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, and the '289 patent (collectively, the "Orbicular Notice Letter Patents").

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 338 of the First Amended Consolidated Complaint, and therefore denies them.

339. On information and belief, Orbicular included in the Orbicular ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Orbicular Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the Orbicular Notice Letter Patents are invalid, unenforceable, and/or will not be infringed by the Orbicular ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 339 of the First Amended Consolidated Complaint, and therefore denies them.

340. Orbicular filed the Orbicular Paragraph IV Certification without adequate justification for asserting that the Orbicular Notice Letter Patents are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Orbicular ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 340 of the First Amended Consolidated Complaint, and therefore denies them.

341. The Orbicular Notice Letter states that Orbicular "has certified to the FDA . . . that [the Patents-in-Suit] are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the drug products described in Orbicular's ANDA." Orbicular Notice

Letter at 2. Orbicular also attached a "detailed statement of the factual and legal bases for Orbicular's assertion of invalidity, unenforceability, and/or noninfringement of [the '451, '028, '081, and '289 patents] regarding revefenacin inhalation solution, 175 mcg/3 mL." Neither the Orbicular Notice Letter nor its attached "detailed statement" provide any substantive invalidity allegation with respect to any of the Orbicular Notice Letter Patents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 341 of the First Amended Consolidated Complaint, and therefore denies them.

342. In the Notice Letter, Orbicular offered confidential access to portions of its ANDA No. 217868, on terms and conditions set forth in the Orbicular Notice Letter ("the Orbicular Offer"). Orbicular requested that Plaintiffs accept the Orbicular Offer before receiving access to the Orbicular ANDA. The Orbicular Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 342 of the First Amended Consolidated Complaint, and therefore denies them.

343. Plaintiffs filed a complaint for infringement of the Orbicular Notice Letter Patents against Orbicular, *inter alia*, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement against, *inter alia*¸ Orbicular Pharmaceutical Technologies Private Limited ("Orbicular"), in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 343 of the First Amended Consolidated Complaint, and therefore denies them.

344. In a letter dated April 12, 2023, purporting to be a notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Orbicular Second Notice Letter"), Orbicular notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had amended ANDA No. 217868 to contain a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Orbicular '531 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Orbicular ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '531 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 344 of the First Amended Consolidated Complaint, and therefore denies them.

345. On information and belief, Orbicular's '531 Patent Paragraph IV Certification states that, in its opinion and to the best of its knowledge, the '531 patent is invalid, unenforceable, and/or will not be infringed by the Orbicular ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 345 of the First Amended Consolidated Complaint, and therefore denies them.

346. Orbicular filed the Orbicular '531 Patent Paragraph IV Certification without adequate justification for asserting that the '531 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Orbicular ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 346 of the First Amended Consolidated Complaint, and therefore denies them.

347. The Orbicular Second Notice Letter states that Orbicular has submitted "an amendment to Abbreviated New Drug Application No. 217868 . . . , which asserts that [the '531 patent] is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Orbicular's ANDA Product." (Orbicular Second Notice Letter at 2.) Orbicular also attached a "detailed statement of the factual and legal bases for the Paragraph IV Certification set forth in Orbicular's ANDA."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 347 of the First Amended Consolidated Complaint, and therefore denies them.

348. The Orbicular Second Notice Letter does not provide a substantive noninfringement defense to the '531 patent in the "detailed statement of the factual and legal bases for the Paragraph IV Certification set forth in Orbicular's ANDA."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 348 of the First Amended Consolidated Complaint, and therefore denies them.

349. Plaintiffs filed a complaint for infringement of the '531 patent against Orbicular in this jurisdiction on May 24, 2023, which was assigned Civil Action No. 23-02843-KMW-AMD, and which was consolidated with this Action on June 26, 2023. (D.I. 94.)

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 349 of the First Amended Consolidated Complaint, and therefore denies them.

350. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

**ANSWER:** Cipla admits that the face of the '948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a "Submission Date" of July 5, 2023 for the '948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 350.

351. In a letter dated August 10, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Orbicular Third Notice Letter"), Orbicular notified Mylan Ireland Limited, Viatris Inc., and Theravance Biopharma R&D IP, LLC that the Orbicular ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Orbicular '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Orbicular ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 351 of the First Amended Consolidated Complaint, and therefore denies them.

352. The Orbicular Third Notice Letter states that the '948 patent "is invalid, unenforceable, and/or will not be infringed by" the Orbicular ANDA Product. (Orbicular Third Notice Letter at 2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 352 of the First Amended Consolidated Complaint, and therefore denies them.

353. Orbicular filed the Orbicular '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Orbicular ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 353 of the First Amended Consolidated Complaint, and therefore denies them.

354. Orbicular also attached to the Orbicular Third Notice Letter a "Detailed Statement of the Factual and Legal Bases for Orbicular's Assertion of Invalidity, Unenforceability, and/or Noninfringement of U.S. Patent No. 11,691,948 Regarding Revefenacin Inhalation Solution, 175 mcg/3 mL."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 354 of the First Amended Consolidated Complaint, and therefore denies them.

355. The Orbicular Third Notice Letter does not provide a substantive invalidity and/or unenforceability defense to the '948 patent in the "Detailed Statement."

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 355 of the First Amended Consolidated Complaint, and therefore denies them.

356. Plaintiffs filed a complaint for infringement of the '948 patent against Orbicular, *inter alia*, in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125.)

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement of the '948 patent against, *inter alia*, Orbicular Pharmaceutical Technologies Private Limited ("Orbicular"), in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-

AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125). Cipla denies the remaining allegations of paragraph 356.

357. On information and belief, the active ingredient of the Orbicular ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions, methods of use, and processes described and claimed in one or more claims of one or more of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 357 of the First Amended Consolidated Complaint, and therefore denies them.

358. On information and belief, Orbicular asserts in ANDA No. 217868 that the Orbicular ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Orbicular, demonstrate the bioequivalence of the Orbicular ANDA Product to YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 358 of the First Amended Consolidated Complaint, and therefore denies them.

359. On information and belief, Orbicular is seeking approval to market the Orbicular ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 359 of the First Amended Consolidated Complaint, and therefore denies them.

360. On information and belief, Orbicular is seeking approval to market the Orbicular ANDA Product for maintenance treatment of patients with COPD.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 360 of the First Amended Consolidated Complaint, and therefore denies them.

361. On information and belief, Orbicular had knowledge of the Orbicular Notice Letter Patents when it submitted and filed ANDA No. 217868.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 361 of the First Amended Consolidated Complaint, and therefore denies them.

362. On information and belief, Orbicular had knowledge of the '531 patent when it submitted and filed the Orbicular '531 Patent Paragraph IV Certification to ANDA No. 217868.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 362 of the First Amended Consolidated Complaint, and therefore denies them.

363. On information and belief, Orbicular had knowledge of the '948 patent when it submitted and filed the Orbicular '948 Patent Paragraph IV Certification to ANDA No. 217868.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 363 of the First Amended Consolidated Complaint, and therefore denies them.

364. On information and belief, Orbicular has actual knowledge as of the date of this First Amended Complaint of the Patents-in-Suit, at least because Plaintiffs have identified all of the Patents-in-Suit to Orbicular as part of this Action.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 364 of the First Amended Consolidated Complaint, and therefore denies them.

365. On information and belief, Orbicular intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of one or more of the Patents-in-Suit upon receiving FDA approval of ANDA No. 217868 and prior to the expiration of one or more of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 365 of the First Amended Consolidated Complaint, and therefore denies them.

366. On information and belief, Orbicular will commercially manufacture, use, offer for sale, and/or sell the Orbicular ANDA Product throughout the United States, import the Orbicular

ANDA Product into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the term of one or more of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 366 of the First Amended Consolidated Complaint, and therefore denies them.

367. On information and belief, Orbicular knows that the Orbicular ANDA Product is especially made or adapted for use in a way that would infringe one or more of the Patents-in-Suit, and is not suitable for substantial non-infringing use. On information and belief, Orbicular knowingly has taken and intends to take active steps to, and will, induce and/or contribute to infringement of one or more claims of one or more of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 367 of the First Amended Consolidated Complaint, and therefore denies them.

368. On information and belief, Orbicular uses processes covered by one or more claims of one or more of the Patents-in-Suit to prepare the Orbicular ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 368 of the First Amended Consolidated Complaint, and therefore denies them.

369. On information and belief, the Orbicular ANDA Product resulting from the processes claimed in one or more of the Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 369 of the First Amended Consolidated Complaint, and therefore denies them.

370. The Orbicular ANDA Product resulting from the processes claimed by one or more of the Patents-in-Suit is not a nonessential and/or trivial component of another product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 370 of the First Amended Consolidated Complaint, and therefore denies them.

371. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Orbicular with respect to infringement of one or more of the Patents-in-Suit.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 371 of the First Amended Consolidated Complaint, and therefore denies them.

372. This action was commenced within 45 days of receipt of the Orbicular Notice Letter.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 372 of the First Amended Consolidated Complaint, and therefore denies them.

**Cipla**

373. In a letter dated January 17, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Cipla Notice Letter"), Cipla notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted ANDA No. 217958 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of the Cipla ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent (collectively, the "Cipla Notice Letter Patents").

**ANSWER:** Cipla admits that in the Cipla Notice Letter, Cipla notified Plaintiffs that it had filed a Paragraph IV Certification with respect to the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent, and was seeking approval from the FDA to engage in the commercial manufacture, use, or sale of Cipla's ANDA Product prior to the expiration of those patents. Cipla denies the remaining allegations of Paragraph 373.

374. On information and belief, Cipla included in the Cipla ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Cipla Paragraph IV Certification") that, in its opinion and to

the best of its knowledge, the Cipla Notice Letter Patents are invalid, unenforceable, and/or will not be infringed by the Cipla ANDA Product.

**ANSWER:** Admitted.

375. Cipla filed the Cipla Paragraph IV Certification without adequate justification for asserting that the Cipla Notice Letter Patents are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Cipla ANDA Product.

**ANSWER:** Denied.

376. In the Cipla Notice Letter, Cipla offered confidential access to portions of its ANDA No. 217958, on terms and conditions set forth in the Cipla Notice Letter ("the Cipla Offer"). Cipla requested that Plaintiffs accept the Cipla Offer before receiving access to the Cipla ANDA. The Cipla Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

**ANSWER:** Cipla admits that it provided an offer of confidential access to Cipla's ANDA with its Notice Letter. Cipla denies the remaining allegations of Paragraph 376.

377. Plaintiffs filed a complaint for infringement of the Cipla Notice Letter Patents against Cipla, *inter alia*, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMWAMD.

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against, *inter alia*¸ Cipla Limited and Cipla USA, Inc., in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

378. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

**ANSWER:** Cipla admits that the face of the '948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a "Submission Date" of July 5, 2023 for the '948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 378.

379. Plaintiffs filed a complaint for infringement of the '948 patent against Cipla, *inter alia*, in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125.)

**ANSWER:** Cipla admits that Plaintiffs filed a complaint for infringement of the '948 patent against, *inter alia*, Cipla Limited and Cipla USA, Inc., in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with this Action on September 29, 2023. (D.I. 125.).

380. In a letter dated August 24, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Cipla Second Notice Letter"), Cipla notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that the Cipla ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Cipla '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Cipla ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

**ANSWER:** Cipla admits that in the Cipla Second Notice Letter, Cipla notified Plaintiffs that it had filed a Paragraph IV Certification with respect to the '948 patent, and was seeking approval from the FDA to engage in the commercial manufacture, use, or sale of Cipla's ANDA Product prior to the expiration of that patent. Cipla denies the remaining allegations of Paragraph 380.

381. The Cipla Second Notice Letter states that "in [Cipla's] opinion and to the best of its knowledge, each claim of the '948 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the drug product described in Cipla's ANDA." (Cipla Second Notice Letter at 3).

**ANSWER:** Admitted.

382. Cipla filed the Cipla '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Cipla ANDA Product.

**ANSWER:** Denied.

383. Cipla also attached to the Cipla Second Notice Letter a "Detailed Factual and Legal Basis for Cipla's Paragraph IV Certification Regarding [the '948 patent]."

**ANSWER:** Admitted.

384. The Cipla Second Notice Letter does not provide a substantive unenforceability defense to the '948 patent in the "Detailed Factual and Legal Basis."

**ANSWER:** Denied.

385. On information and belief, the active ingredient of the Cipla ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions, methods of use, and processes described and claimed in one or more claims of the Patents-in-Suit.

**ANSWER:** Denied.

386. On information and belief, Cipla asserts in ANDA No. 217958 that the Cipla ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Cipla, demonstrate the bioequivalence of the Cipla ANDA Product to YUPELRI®.

**ANSWER:** Paragraph 386 contains legal conclusions to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 386.

387. On information and belief, Cipla is seeking approval to market the Cipla ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Cipla admits that it is seeking approval to market the Cipla ANDA Product. Cipla denies the remaining allegations of Paragraph 387.

388. On information and belief, Cipla is seeking approval to market the Cipla ANDA Product for maintenance treatment of patients with COPD.

**ANSWER:** Admitted.

389. On information and belief, Cipla had knowledge of the Cipla Notice Letter Patents when it submitted and filed ANDA No. 217958.

**ANSWER:** Admitted.

390. On information and belief, Cipla had knowledge of the '948 patent when it submitted and filed the Cipla '948 Patent Paragraph IV Certification to ANDA No. 217958.

**ANSWER:** Admitted.

391. On information and belief, Cipla has actual knowledge as of the date of this First Amended Complaint of the Patents-in-Suit, at least because Plaintiffs have identified all of the Patents-in-Suit to Cipla as part of this Action.

**ANSWER:** Admitted.

392. On information and belief, Cipla intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the Patents-in-Suit upon receiving FDA approval of ANDA No. 217958 and prior to the expiration of the Patents-in-Suit.

**ANSWER:** Denied.

393. On information and belief, Cipla will commercially manufacture, use, offer for sale, and/or sell the Cipla ANDA Product throughout the United States, import the Cipla ANDA Product into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the Patents-in-Suit.

**ANSWER:** Cipla denies the allegations of Paragraph 393 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

394. On information and belief, Cipla knows that the Cipla ANDA Product is especially made or adapted for use in a way that would infringe the Patents-in-Suit, and is not suitable for substantial non-infringing use. On information and belief, Cipla knowingly has taken and intends to take active steps to, and will, induce and/or contribute to infringement of one or more claims of the Patents-in-Suit.

**ANSWER:** Denied.

395. On information and belief, Cipla uses processes covered by one or more claims of the Patents-in-Suit to prepare the Cipla ANDA Product.

**ANSWER:** Denied.

396. On information and belief, the Cipla ANDA Product resulting from the processes claimed in one or more Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more Patents-in-Suit.

**ANSWER:** Denied.

397. The Cipla ANDA product resulting from the processes claimed by one or more Patents-in-Suit is not a nonessential and/or trivial component of another product.

**ANSWER:** Denied.

398. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Cipla with respect to infringement of the Patents-in-Suit.

**ANSWER:** Cipla admits that actual, substantial, and continuing justiciable case or controversy exists between Cipla and Plaintiffs. Cipla denies the remaining allegations of Paragraph 398.

399. This action was commenced within 45 days of receipt of the Cipla Notice Letter.

**ANSWER:** Admitted.

**COUNT I**
**INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY EUGIA**

400. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

401. Eugia's submission of ANDA No. 218128 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Eugia ANDA Product in/into the United States prior to the expiration of the '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 401 of the First Amended Consolidated Complaint, and therefore denies them.

402. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 402 of the First Amended Consolidated Complaint, and therefore denies them.

403. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United

States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 403 of the First Amended Consolidated Complaint, and therefore denies them.

404. On information and belief, Eugia intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '451 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 404 of the First Amended Consolidated Complaint, and therefore denies them.

405. On information and belief, Eugia had knowledge of the '451 patent when it submitted ANDA No. 218128. Eugia's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 405 of the First Amended Consolidated Complaint, and therefore denies them.

406. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '451 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 406 of the First Amended Consolidated Complaint, and therefore denies them.

407. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 407 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT II**

**INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY EUGIA**

408. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

409. Eugia's submission of ANDA No. 218128 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Eugia ANDA Product in/into the United States prior to the expiration of the '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 409 of the First Amended Consolidated Complaint, and therefore denies them.

410. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 410 of the First Amended Consolidated Complaint, and therefore denies them.

411. On information and belief, Eugia intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '028 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 411 of the First Amended Consolidated Complaint, and therefore denies them.

412. On information and belief, Eugia had knowledge of the '028 patent when it submitted ANDA No. 218128. Eugia's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 412 of the First Amended Consolidated Complaint, and therefore denies them.

413. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '028 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 413 of the First Amended Consolidated Complaint, and therefore denies them.

414. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 414 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT III**
**INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY EUGIA**

415. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

416. Eugia's submission of ANDA No. 218128 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Eugia ANDA Product in/into the United States prior to the expiration of the '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 416 of the First Amended Consolidated Complaint, and therefore denies them.

417. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 417 of the First Amended Consolidated Complaint, and therefore denies them.

418. On information and belief, Eugia intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 418 of the First Amended Consolidated Complaint, and therefore denies them.

419. On information and belief, Eugia had knowledge of the '081 patent when it submitted ANDA No. 218128. Eugia's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 419 of the First Amended Consolidated Complaint, and therefore denies them.

420. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '081 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 420 of the First Amended Consolidated Complaint, and therefore denies them.

421. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 421 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT IV**
**INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY EUGIA**

422. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

423. Eugia's submission of ANDA No. 218128 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Eugia ANDA Product in/into the United States prior to the expiration of the '289 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 423 of the First Amended Consolidated Complaint, and therefore denies them.

424. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 424 of the First Amended Consolidated Complaint, and therefore denies them.

425. On information and belief, Eugia intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '289 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 425 of the First Amended Consolidated Complaint, and therefore denies them.

426. On information and belief, Eugia had knowledge of the '289 patent when it submitted ANDA No. 218128. Eugia's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 426 of the First Amended Consolidated Complaint, and therefore denies them.

427. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '289 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 427 of the First Amended Consolidated Complaint, and therefore denies them.

428. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 428 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT V**
**INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY EUGIA**

429. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

430. Eugia's submission of ANDA No. 218128 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Eugia ANDA Product in/into the United States prior to the expiration of the '531 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A). 431. Unless enjoined, upon FDA approval of Eugia's ANDA No. 218128, Eugia will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 430 of the First Amended Consolidated Complaint, and therefore denies them.

431. Unless enjoined, upon FDA approval of Eugia's ANDA No. 218128, Eugia will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 431 of the First Amended Consolidated Complaint, and therefore denies them.

432. On information and belief, upon FDA approval of Eugia's ANDA No. 218128, Eugia intends to manufacture, market, sell, and offer to sell Eugia's ANDA Product with an FDA-approved package insert that will direct healthcare providers and patients in the use of Eugia's ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 432 of the First Amended Consolidated Complaint, and therefore denies them.

433. On information and belief, Eugia will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Eugia knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '531 patent by marketing Eugia's ANDA Product with the FDA-approved package insert.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 433 of the First Amended Consolidated Complaint, and therefore denies them.

434. The '531 patent has one independent claim, claim 1, which states:

> 1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:
>
> (a) selecting a patient having chronic obstructive pulmonary disease for treatment based on the patient having a peak inspiratory flow rate less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50 percent; and
>
> (b) administering a pharmaceutical composition comprising about 175 µg of revefenacin, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

**ANSWER:** Admitted.

435 A healthcare provider will directly infringe one of more of the claims of the '531 patent. Specifically, a healthcare provider administering Eugia's ANDA Product in accordance with Eugia's package insert will perform all of the steps of one or more claims of the '531 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 435 of the First Amended Consolidated Complaint, and therefore denies them.

436. FDA regulations require that approved drug products include prescribing information reciting the FDA-approved indication(s) for the drug and related instructions for healthcare providers to safely and effectively administer the drug. *See* 21 C.F.R. § 201.56(a)(1)¬(3), (d)(1); 21 C.F.R. § 201.57(a)-(c).

**ANSWER:** Paragraph 436 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 436.

437. Consistent with FDA regulations, the package insert for YUPELRI® includes prescribing information that recites the FDA-approved indication for YUPELRI® and provides instructions for healthcare providers and patients to safely and effectively administer YUPELRI®.

**ANSWER:** Paragraph 437 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 437.

438. The package insert for Eugia's ANDA Product will be substantially similar to the package insert for YUPELRI® in all material respects.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 438 of the First Amended Consolidated Complaint, and therefore denies them.

439. Providers of revefenacin review and follow the package inserts for the revefenacin products they use to treat their patients.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 439 of the First Amended Consolidated Complaint, and therefore denies them.

440. On information and belief, Eugia is seeking approval to market its ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 440 of the First Amended Consolidated Complaint, and therefore denies them.

441. The YUPELRI® package insert instructs that YUPELRI® is "indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." (Ex. F at § 1).

**ANSWER:** Cipla admits that the YUPELRI® label recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." The remainder of Paragraph 441 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the remaining allegations of Paragraph 441.

442. The "Dosage and Administration" section of the YUPELRI® package instructs that the "recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." (Ex. F at § 2).

**ANSWER:** Cipla admits the YUPELRI ® label recites that "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 442 of the First Amended Consolidated Complaint, and therefore denies them.

443. The "Dosage Form and Strengths" section of the YUPELRI® package insert states that YUPELRI® is an "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." (Ex. F at § 3).

**ANSWER:** Cipla admits that the YUPELRI® label recites "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations containing in Paragraph 443 of the First Amended Consolidated Complaint, and therefore denies them.

444. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 444 of the First Amended Consolidated Complaint, and therefore denies them.

445. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 445 of the First Amended Consolidated Complaint, and therefore denies them.

446. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV1 of 55%. (*Id.*)

**ANSWER:** Cipla admits that the YUPELRI® label recites "[a]t screening, the mean post-bronchodilator percent predicted FEV1 was 55% (range: 10% to 90%), and the post-broncodilator FEV1/FVC ratio was 0.54 (range: 0.3 to 0.7)." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 446 of the First Amended Consolidated Complaint, and therefore denies them.

447. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV1 of equal to or greater than 30% and less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 447 of the First Amended Consolidated Complaint, and therefore denies them.

448. A healthcare provider, or a patient at the direction of a healthcare provider, will administer Eugia's ANDA Product to the patient once daily using a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 448 of the First Amended Consolidated Complaint, and therefore denies them.

449. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

**ANSWER:** Cipla admits that the YUPELRI® label recites "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 449 of the First Amended Consolidated Complaint, and therefore denies them.

450. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient's ability to use an inhaler.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 450 of the First Amended Consolidated Complaint, and therefore denies them.

451. It is known that successful use of dry powder inhalers such as the HandiHaler® requires a PIFR of 60 L/min.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 451 of the First Amended Consolidated Complaint, and therefore denies them.

452. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. *See, e.g.*, Mahler 2017; Mahler 2014.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 452 of the First Amended Consolidated Complaint, and therefore denies them.

453. On information and belief, Eugia specifically intends that its ANDA product, if marketed, would be administered to some patients with moderate to severe COPD having a PIFR of less than about 60 L/min and FEV1 of less than 50%, using a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 453 of the First Amended Consolidated Complaint, and therefore denies them.

454. On information and belief, Eugia knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 454 of the First Amended Consolidated Complaint, and therefore denies them.

455. On information and belief, Eugia knows, and specifically intends, that some healthcare providers will select patients for treatment with its proposed ANDA product, if marketed, based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 455 of the First Amended Consolidated Complaint, and therefore denies them.

456. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '531 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 456 of the First Amended Consolidated Complaint, and therefore denies them.

457. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 457 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT VI**
**INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY EUGIA**

458. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

459. Eugia's submission of ANDA No. 218128 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Eugia ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 459 of the First Amended Consolidated Complaint, and therefore denies them.

460. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 460 of the First Amended Consolidated Complaint, and therefore denies them.

461. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 461 of the First Amended Consolidated Complaint, and therefore denies them.

462. On information and belief, Eugia intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, i.e., prior to the expiration of the '948 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 462 of the First Amended Consolidated Complaint, and therefore denies them.

463. On information and belief, Eugia had knowledge of the '948 patent when it submitted the Eugia '948 Patent Paragraph IV Certification as part of ANDA No. 218128. Eugia's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 463 of the First Amended Consolidated Complaint, and therefore denies them.

464. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '948 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 464 of the First Amended Consolidated Complaint, and therefore denies them.

465. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 465 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT VII**
**INFRINGEMENT OF U.S. PATENT NO. 8,017,783 BY EUGIA**

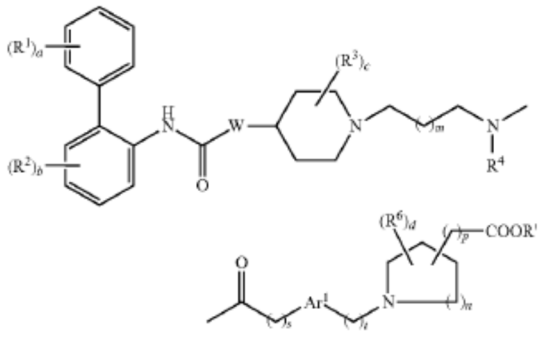
466. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

467. Claim 1 of the '783 patent recites:

1. A compound of formula XVIII:

XVIII



wherein:

a is 0 or an integer of from 1 to 5;

each $R^1$ is independently selected from (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (3-6C)cycloalkyl, cyano, halo, —$OR^{1a}$, $C(O)OR^{1b}$, —$SR^{1c}$, —$S(O)R^{1d}$, —$S(O)_2R^{1e}$, —$NR^{1f}R^{1g}$, —$NR^{1h}S(O)_2R^{1i}$, and —$NR^{1j}C(O)R^{1k}$; where each of $R^{1a}$, $R^{1b}$, $R^{1c}$, $R^{1d}$, $R^{1e}$, $R^{1f}$, $R^{1g}$, $R^{1h}$, $R^{1i}$, $R^{1j}$, and $R^{1k}$ is independently hydrogen, (1-4C)alkyl or phenyl(1-4C)alkyl;

b is 0 or an integer of from 1 to 4;

each $R^2$ is independently selected from (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (3-6C)cycloalkyl, cyano, halo, —$OR^{2a}$, —$C(O)OR^{2b}$, —$SR^{2c}$, —$S(O)R^{2d}$, —$S(O)_2R^{2e}$, —$NR^{2f}R^{2g}$, —$NR^{2h}S(O)_2R^{2i}$, and —$NR^{2j}C(O)R^{2k}$; where each of $R^{2a}$, $R^{2b}$, $R^{2c}$, $R^{2d}$, $R^{2e}$, $R^{2f}$, $R^{2g}$, $R^{2h}$, $R^{2i}$, $R^{2j}$, and $R^{2k}$ is independently hydrogen, (1-4C)alkyl or phenyl(1-4C)alkyl;

W represents O or $NW^a$, where $W^a$ is hydrogen or (1-4C)alkyl;

c is 0 or an integer from 1 to 5;

each $R^3$ independently represents (1-4C)alkyl or two $R^3$ groups are joined to form (1-3C)alkylene, (2-3C)alkenylene or oxiran-2,3-diyl;

m is 0 or 1;

$R^4$ is selected from hydrogen, (1-4C)alkyl, and (3-4C)cycloalkyl;

s is 0, 1 or 2;

$Ar^1$ represents a phenylene group or a (3-5C)heteroarylene group containing 1 or 2 heteroatoms independently selected from oxygen, nitrogen, and sulfur; wherein the phenylene or heteroarylene group is substituted with $(R^5)_q$ where q is 0 or an integer from 1 to 4 and each $R^5$ is independently selected from halo, hydroxy, (1-4C)alkyl, and (1-4C)alkoxy;

t is 0, 1 or 2;

n is 0 or an integer from 1 to 3;

d is 0 or an integer from 1 to 4;

each $R^6$ independently represents fluoro or (1-4C)alkyl;

p is 0 or 1; and

R' is selected from hydrogen, —$CH_3$, and —$CH_2CH_3$;

wherein each alkyl and alkoxy group in $R^1$, $R^{1a-1k}$, $R^2$, $R^{2a-2k}$, $R^3$, $R^5$, and $R^6$ is optionally substituted with 1 to 5 fluoro substituents;

or a pharmaceutically acceptable salt or stereoisomer thereof.

**ANSWER:** Admitted.

468. According to the YUPELRI® package insert, in Section 12.3, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 468 of the First Amended Consolidated Complaint, and therefore denies them.

469. According to the YUPELRI® package insert, in Section 12.3, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly[.]" Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 469 of the First Amended Consolidated Complaint, and therefore denies them.

470. On information and belief, when a patient uses the Eugia ANDA Product, the revefenacin contained in the Eugia ANDA Product will undergo hydrolysis of the primary amide to form a carboxcylic acid.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 470 of the First Amended Consolidated Complaint, and therefore denies them.

471. On information and belief, the compound resulting from that reaction is a compound within the scope of Claim 1 of the '783 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 471 of the First Amended Consolidated Complaint, and therefore denies them.

472. The commercial use of the product that is the subject of Eugia's ANDA No. 218128 will constitute an act of infringement of the '783 patent under 35 U.S.C. § 271(b) and (c) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 472 of the First Amended Consolidated Complaint, and therefore denies them.

473. On information and belief, Eugia intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '783 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 473 of the First Amended Consolidated Complaint, and therefore denies them.

474. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '783 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 474 of the First Amended Consolidated Complaint, and therefore denies them.

475. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 475 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT VIII**
**INFRINGEMENT OF U.S. PATENT NO. 9,249,099 BY EUGIA**

476. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

477. Claim 1 of the '099 patent recites:

> 1. A crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1 ylmethyl)benzoyl]methylamino}ethyl)piperidin-4-yl qester, characterized by a powder x-ray diffraction pattern having:
>
> (a) two or more diffraction peaks at 2θ values selected from 4.7±0.2, 9.6±0.2, 12.7±0.2, 13.7±0.2, 16.7±0.2, 17.4±0.2, 18.5±0.2, 19.4±0.2, 20.8±0.2, 21.4±0.2, 24.2±0.2, and 25.6±0.2; or
>
> (b) two or more diffraction peaks at 2θ values selected from 4.6±0.2, 9.3±0.2, 12.9±0.2, 13.6±0.2, 14.0±0.2, 14.6±0.2, 16.5±0.2, 18.6±0.2, 19.1±0.2, 20.9±0.2, 22.1±0.2, 22.7±0.2, and 25.7±0.2.

**ANSWER:** Admitted.

478. On information and belief, Eugia uses some amount of a compound recited in claim 1 of the '099 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 478 of the First Amended Consolidated Complaint, and therefore denies them.

479. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Eugia's ANDA No. 218128 will constitute acts of infringement of the '099 patent under 35 U.S.C. §§ 271(a) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 479 of the First Amended Consolidated Complaint, and therefore denies them.

480. On information and belief, Eugia intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of

the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '099 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 480 of the First Amended Consolidated Complaint, and therefore denies them.

481. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '099 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 481 of the First Amended Consolidated Complaint, and therefore denies them.

482. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 482 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT IX**
**INFRINGEMENT OF U.S. PATENT NO. 10,100,013 BY EUGIA**

483. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

484. Claim 1 of the '013 patent recites:

> 1. A method for preparing a pharmaceutical composition for use in a nebulizer inhaler, the method comprising dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester in an aqueous pharmaceutical carrier to form an aqueous solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Admitted.

485. On information and belief, the manufacture of Eugia's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 485 of the First Amended Consolidated Complaint, and therefore denies them.

486. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Eugia's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '013 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 486 of the First Amended Consolidated Complaint, and therefore denies them.

487. Plaintiffs have requested relevant discovery from Eugia to confirm these characteristics of Eugia's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Eugia's ANDA Product—but have not received said discovery as of the date of this First Amended Complaint. Eugia has an affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 487 of the First Amended Consolidated Complaint, and therefore denies them.

488. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Eugia's ANDA No. 218128 will constitute acts of infringement of the '013 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 488 of the First Amended Consolidated Complaint, and therefore denies them.

489. On information and belief, Eugia intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon

the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '013 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 489 of the First Amended Consolidated Complaint, and therefore denies them.

490. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '013 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 490 of the First Amended Consolidated Complaint, and therefore denies them.

491. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 491 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT X**
**INFRINGEMENT OF U.S. PATENT NO. 11,649,209 BY EUGIA**

492. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

493. Claim 1 of the '209 patent recites:

1. A process for preparing a pharmaceutical composition, the process comprising:

dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-l-ylmethyl)benzoyl)]methylamino}-ethyl)piperidin-4-yl ester in a solvent to form a solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Amitted.

494. On information and belief, the manufacture of Eugia's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 494 of the First Amended Consolidated Complaint, and therefore denies them.

495. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Eugia's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '209 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 495 of the First Amended Consolidated Complaint, and therefore denies them.

496. Plaintiffs have requested relevant discovery from Eugia to confirm these characteristics of Eugia's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Eugia's ANDA Product—but have not received said discovery as of the date of this First Amended Complaint. Eugia has an affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 496 of the First Amended Consolidated Complaint, and therefore denies them.

497. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Eugia's ANDA No. 218128 will constitute acts of infringement of the '209 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 497 of the First Amended Consolidated Complaint, and therefore denies them.

498. On information and belief, Eugia intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '209 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 498 of the First Amended Consolidated Complaint, and therefore denies them.

499. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '209 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 499 of the First Amended Consolidated Complaint, and therefore denies them.

500. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 500 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XI**
**INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY MANKIND**

501. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

502. Mankind's submission of ANDA No. 218089 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Mankind ANDA Product in/into the United States prior to the expiration of the '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 502 of the First Amended Consolidated Complaint, and therefore denies them.

503. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 503 of the First Amended Consolidated Complaint, and therefore denies them.

504. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 504 of the First Amended Consolidated Complaint, and therefore denies them.

505. On information and belief, Mankind intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, i.e., prior to the expiration of the '451 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 505 of the First Amended Consolidated Complaint, and therefore denies them.

506. On information and belief, Mankind had knowledge of the '451 patent when it submitted ANDA No. 218089. Mankind's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 506 of the First Amended Consolidated Complaint, and therefore denies them.

507. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '451 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 507 of the First Amended Consolidated Complaint, and therefore denies them.

508. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 508 of the First Amended Consolidated Complaint, and therefore denies them.

## COUNT XII
## INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY MANKIND

509. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

510. Mankind's submission of ANDA No. 218089 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Mankind ANDA Product in/into the United States prior to the expiration of the '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 510 of the First Amended Consolidated Complaint, and therefore denies them.

511. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 511 of the First Amended Consolidated Complaint, and therefore denies them.

512. On information and belief, Mankind intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, i.e., prior to the expiration of the '028 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 512 of the First Amended Consolidated Complaint, and therefore denies them.

513. On information and belief, Mankind had knowledge of the '028 patent when it submitted ANDA No. 218089. Mankind's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 513 of the First Amended Consolidated Complaint, and therefore denies them.

514. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '028 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 514 of the First Amended Consolidated Complaint, and therefore denies them.

515. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 515 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XIII**
**INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY MANKIND**

516. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

517. Mankind's submission of ANDA No. 218089 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Mankind ANDA Product in/into the United States prior to the expiration of the '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 517 of the First Amended Consolidated Complaint, and therefore denies them.

518. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 518 of the First Amended Consolidated Complaint, and therefore denies them.

519. On information and belief, Mankind intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 519 of the First Amended Consolidated Complaint, and therefore denies them.

520. On information and belief, Mankind had knowledge of the '081 patent when it submitted ANDA No. 218089. Mankind's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 520 of the First Amended Consolidated Complaint, and therefore denies them.

521. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '081 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 521 of the First Amended Consolidated Complaint, and therefore denies them.

522. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 522 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XIV**
**INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY MANKIND**

523. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

524. Mankind's submission of ANDA No. 218089 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Mankind ANDA Product in/into the United States prior to the expiration of the '289 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 524 of the First Amended Consolidated Complaint, and therefore denies them.

525. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 525 of the First Amended Consolidated Complaint, and therefore denies them.

526. On information and belief, Mankind intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, i.e., prior to the expiration of the '289 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 526 of the First Amended Consolidated Complaint, and therefore denies them.

527. On information and belief, Mankind had knowledge of the '289 patent when it submitted ANDA No. 218089. Mankind's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 527 of the First Amended Consolidated Complaint, and therefore denies them.

528. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '289 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 528 of the First Amended Consolidated Complaint, and therefore denies them.

529. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 529 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XV**
**INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY MANKIND**

530. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

531. Mankind's submission of ANDA No. 218089 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Mankind ANDA Product in/into the United States prior to the expiration of the '531 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 531 of the First Amended Consolidated Complaint, and therefore denies them.

532. Unless enjoined, upon FDA approval of Mankind's ANDA No. 218089, Mankind will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 532 of the First Amended Consolidated Complaint, and therefore denies them.

533. On information and belief, upon FDA approval of Mankind's ANDA No. 218089, Mankind intends to manufacture, market, sell, and offer to sell Mankind's ANDA Product with an FDA-approved package insert that will direct healthcare providers and patients in the use of Mankind's ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 533 of the First Amended Consolidated Complaint, and therefore denies them.

534. On information and belief, Mankind will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Mankind knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '531 patent by marketing Mankind's ANDA Product with the FDA-approved package insert.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 534 of the First Amended Consolidated Complaint, and therefore denies them.

535. The '531 patent has one independent claim, claim 1, which states:

1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:

(a) selecting a patient having chronic obstructive pulmonary disease for treatment based on the patient having a peak inspiratory flow rate less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50 percent; and

(b) administering a pharmaceutical composition comprising about 175 µg of revefenacin, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

**ANSWER:** Admitted.

536. A healthcare provider will directly infringe one of more of the claims of the '531 patent. Specifically, a healthcare provider administering Mankind's ANDA Product in accordance with Mankind's package insert will perform all of the steps of one or more claims of the '531 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 536 of the First Amended Consolidated Complaint, and therefore denies them.

537. FDA regulations require that approved drug products include prescribing information reciting the FDA-approved indication(s) for the drug and related instructions for healthcare providers to safely and effectively administer the drug. See 21 C.F.R. § 201.56(a)(1)¬(3), (d)(1); 21 C.F.R. § 201.57(a)-(c).

**ANSWER:** Paragraph 537 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 537.

538. Consistent with FDA regulations, the package insert for YUPELRI® includes prescribing information that recites the FDA-approved indication for YUPELRI® and provides instructions for healthcare providers and patients to safely and effectively administer YUPELRI®.

**ANSWER:** Paragraph 538 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 538.

539. The package insert for Mankind's ANDA Product will be substantially similar to the package insert for YUPELRI® in all material respects.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 539 of the First Amended Consolidated Complaint, and therefore denies them.

540. Providers of revefenacin review and follow the package inserts for the revefenacin products they use to treat their patients.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 540 of the First Amended Consolidated Complaint, and therefore denies them.

541. On information and belief, Mankind is seeking approval to market its ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 541 of the First Amended Consolidated Complaint, and therefore denies them.

542. The YUPELRI® package insert instructs that YUPELRI® is "indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." (Ex. F at § 1).

**ANSWER:** Cipla admits that the YUPELRI® label recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." The remainder of Paragraph 542 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the remaining allegations of Paragraph 542.

543. The "Dosage and Administration" section of the YUPELRI® package insert instructs that the "recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." (Ex. F at § 2).

**ANSWER:** Cipla admits the YUPELRI ® label recites that "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by

nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 543 of the First Amended Consolidated Complaint, and therefore denies them.

544. The "Dosage Form and Strengths" section of the YUPELRI® package insert states that YUPELRI® is an "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." (Ex. F at § 3).

**ANSWER:** Cipla admits that the YUPELRI® label recites "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations containing in Paragraph 544 of the First Amended Consolidated Complaint, and therefore denies them.

545. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 545 of the First Amended Consolidated Complaint, and therefore denies them.

546. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 546 of the First Amended Consolidated Complaint, and therefore denies them.

547. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV1 of 55%. (Id.)

**ANSWER:** Cipla admits that the YUPELRI® label recites "[a]t screening, the mean post-bronchodilator percent predicted FEV1 was 55% (range: 10% to 90%), and the post-broncodilator FEV1/FVC ratio was 0.54 (range: 0.3 to 0.7)." Cipla is without knowledge or

information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 547 of the First Amended Consolidated Complaint, and therefore denies them.

548. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV1 of equal to or greater than 30% and less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 548 of the First Amended Consolidated Complaint, and therefore denies them.

549. A healthcare provider, or a patient at the direction of a healthcare provider, will administer Mankind's ANDA Product to the patient once daily using a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 549 of the First Amended Consolidated Complaint, and therefore denies them.

550. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

**ANSWER:** Cipla admits that the YUPELRI® label recites "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 550 of the First Amended Consolidated Complaint, and therefore denies them.

551. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient's ability to use an inhaler.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 551 of the First Amended Consolidated Complaint, and therefore denies them.

552. It is known that successful use of dry powder inhalers such as the HandiHaler® requires a PIFR of 60 L/min.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 552 of the First Amended Consolidated Complaint, and therefore denies them.

553. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. See, e.g., Mahler 2017; Mahler 2014.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 553 of the First Amended Consolidated Complaint, and therefore denies them.

554. On information and belief, Mankind specifically intends that its ANDA product, if marketed, would be administered to some patients with moderate to severe COPD having a PIFR of less than about 60 L/min and FEV1 of less than 50%, using a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 554 of the First Amended Consolidated Complaint, and therefore denies them.

555. On information and belief, Mankind knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 555 of the First Amended Consolidated Complaint, and therefore denies them.

556. On information and belief, Mankind knows, and specifically intends, that some healthcare providers will select patients for treatment with its proposed ANDA product, if marketed, based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 556 of the First Amended Consolidated Complaint, and therefore denies them.

557. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '531 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 557 of the First Amended Consolidated Complaint, and therefore denies them.

558. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 558 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XVI**
**INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY MANKIND**

559. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

560. Mankind's submission of ANDA No. 218089 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Mankind ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 560 of the First Amended Consolidated Complaint, and therefore denies them.

561. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 561 of the First Amended Consolidated Complaint, and therefore denies them.

562. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 562 of the First Amended Consolidated Complaint, and therefore denies them.

563. On information and belief, Mankind intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, *i.e.*, prior to the expiration of the '948 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 563 of the First Amended Consolidated Complaint, and therefore denies them.

564. On information and belief, Mankind had knowledge of the '948 patent when it submitted the Mankind '948 Patent Paragraph IV Certification as part of ANDA No. 218089. Mankind's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 564 of the First Amended Consolidated Complaint, and therefore denies them.

565. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '948 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 565 of the First Amended Consolidated Complaint, and therefore denies them.

566. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 566 of the First Amended Consolidated Complaint, and therefore denies them.

## COUNT XVII
## INFRINGEMENT OF U.S. PATENT NO. 8,017,783 BY MANKIND

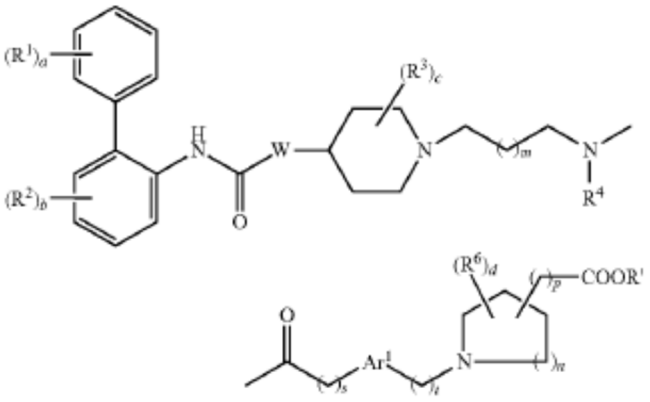
567. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

568. Claim 1 of the ’783 patent recites:

1. A compound of formula XVIII:

XVIII



wherein:

a is 0 or an integer of from 1 to 5;

each $R^1$ is independently selected from (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (3-6C)cycloalkyl, cyano, halo, —$OR^{1a}$, $C(O)OR^{1b}$, —$SR^{1c}$, —$S(O)R^{1d}$, —$S(O)_2R^{1e}$, —$NR^{1f}R^{1g}$, —$NR^{1h}S(O)_2R^{1i}$, and —$NR^{1j}C(O)R^{1k}$; where each of $R^{1a}$, $R^{1b}$, $R^{1c}$, $R^{1d}$, $R^{1e}$, $R^{1f}$, $R^{1g}$, $R^{1h}$, $R^{1i}$, $R^{1j}$, and $R^{1k}$ is independently hydrogen, (1-4C)alkyl or phenyl(1-4C)alkyl;

b is 0 or an integer of from 1 to 4;

each $R^2$ is independently selected from (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (3-6C)cycloalkyl, cyano, halo, —$OR^{2a}$, —$C(O)OR^{2b}$, —$SR^{2c}$, —$S(O)R^{2d}$, —$S(O)_2R^{2e}$, —$NR^{2f}R^{2g}$, —$NR^{2h}S(O)_2R^{2i}$, and —$NR^{2j}C(O)R^{2k}$; where each of $R^{2a}$, $R^{2b}$, $R^{2c}$, $R^{2d}$, $R^{2e}$, $R^{2f}$, $R^{2g}$, $R^{2h}$, $R^{2i}$, $R^{2j}$, and $R^{2k}$ is independently hydrogen, (1-4C)alkyl or phenyl(1-4C)alkyl;

W represents O or $NW^a$, where $W^a$ is hydrogen or (1-4C)alkyl;

c is 0 or an integer from 1 to 5;

each $R^3$ independently represents (1-4C)alkyl or two $R^3$ groups are joined to form (1-3C)alkylene, (2-3C)alkenylene or oxiran-2,3-diyl;

m is 0 or 1;

$R^4$ is selected from hydrogen, (1-4C)alkyl, and (3-4C)cycloalkyl;

s is 0, 1 or 2;

$Ar^1$ represents a phenylene group or a (3-5C)heteroarylene group containing 1 or 2 heteroatoms independently

selected from oxygen, nitrogen, and sulfur; wherein the phenylene or heteroarylene group is substituted with $(R^5)_q$ where q is 0 or an integer from 1 to 4 and each $R^5$ is independently selected from halo, hydroxy, (1-4C) alkyl, and (1-4C)alkoxy;
t is 0, 1 or 2;
n is 0 or an integer from 1 to 3;
d is 0 or an integer from 1 to 4;
each $R^6$ independently represents fluoro or (1-4C)alkyl;
p is 0 or 1; and
R' is selected from hydrogen, $—CH_3$, and $—CH_2CH_3$;
wherein each alkyl and alkoxy group in $R^1$, $R^{1a-1k}$, $R^2$, $R^{2a-2k}$, $R^3$, $R^5$, and $R^6$ is optionally substituted with 1 to 5 fluoro substituents;
or a pharmaceutically acceptable salt or stereoisomer thereof.

**ANSWER:** Admitted.

569. According to the YUPELRI® package insert, in Section 12.3, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 569 of the First Amended Consolidated Complaint, and therefore denies them.

570. According to the YUPELRI® package insert, in Section 12.3, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly[.]" Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 570 of the First Amended Consolidated Complaint, and therefore denies them.

571. On information and belief, when a patient uses the Mankind ANDA Product, the revefenacin contained in the Mankind ANDA Product will undergo hydrolysis of the primary amide to form a carboxcylic acid.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 571 of the First Amended Consolidated Complaint, and therefore denies them.

572. On information and belief, the compound resulting from that reaction is a compound within the scope of Claim 1 of the '783 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 572 of the First Amended Consolidated Complaint, and therefore denies them.

573. The commercial use of the product that is the subject of Mankind's ANDA No. 218089 will constitute an act of infringement of the '783 patent under 35 U.S.C. § 271(b) and (c) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 573 of the First Amended Consolidated Complaint, and therefore denies them.

574. On information and belief, Mankind intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, *i.e.*, prior to the expiration of the '783 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 574 of the First Amended Consolidated Complaint, and therefore denies them.

575. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '783 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 575 of the First Amended Consolidated Complaint, and therefore denies them.

576. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 576 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XVIII**
**INFRINGEMENT OF U.S. PATENT NO. 9,249,099 BY MANKIND**

577. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

578. Claim 1 of the '099 patent recites:

> 1. A crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-
>
> ylmethyl)benzoyl]methylamino}ethyl)piperidin-4-yl ester, characterized by a powder x-ray diffraction pattern having:
>
> (a) two or more diffraction peaks at 2θ values selected from 4.7±0.2, 9.6±0.2, 12.7±0.2, 13.7±0.2, 16.7±0.2, 17.4±0.2, 18.5±0.2, 19.4±0.2, 20.8±0.2, 21.4±0.2, 24.2±0.2, and 25.6±0.2; or
>
> (b) two or more diffraction peaks at 2θ values selected from 4.6±0.2, 9.3±0.2, 12.9±0.2, 13.6±0.2, 14.0±0.2, 14.6±0.2, 16.5±0.2, 18.6±0.2, 19.1±0.2, 20.9±0.2, 22.1±0.2, 22.7±0.2, and 25.7±0.2.

**ANSWER:** Admitted.

579. On information and belief, Mankind uses some amount of a compound recited in claim 1 of the '099 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 579 of the First Amended Consolidated Complaint, and therefore denies them.

580. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Mankind's ANDA No. 218089 will constitute acts of infringement of the '099 patent under 35 U.S.C. §§ 271(a) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 580 of the First Amended Consolidated Complaint, and therefore denies them.

581. On information and belief, Mankind intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, *i.e.*, prior to the expiration of the '099 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 581 of the First Amended Consolidated Complaint, and therefore denies them.

582. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '099 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 582 of the First Amended Consolidated Complaint, and therefore denies them.

583. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 583 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XIX**

**INFRINGEMENT OF U.S. PATENT NO. 10,100,013 BY MANKIND**

584. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

585. Claim 1 of the '013 patent recites:

> 1. A method for preparing a pharmaceutical composition for use in a nebulizer inhaler, the method comprising dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino} ethyl)piperidin-4-yl ester in an aqueous pharmaceutical carrier to form an aqueous solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Admitted.

586. On information and belief, the manufacture of Mankind's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 586 of the First Amended Consolidated Complaint, and therefore denies them.

587. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Mankind's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '013 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 587 of the First Amended Consolidated Complaint, and therefore denies them.

588. Plaintiffs have requested relevant discovery from Mankind to confirm these characteristics of Mankind's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Mankind's ANDA Product—but have not received said discovery as of the date of this First Amended Complaint. Mankind has an

affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 588 of the First Amended Consolidated Complaint, and therefore denies them.

589. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Mankind's ANDA No. 218089 will constitute acts of infringement of the '013 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 589 of the First Amended Consolidated Complaint, and therefore denies them.

590. On information and belief, Mankind intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, i.e., prior to the expiration of the '013 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 590 of the First Amended Consolidated Complaint, and therefore denies them.

591. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '013 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 591 of the First Amended Consolidated Complaint, and therefore denies them.

592. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 592 of the First Amended Consolidated Complaint, and therefore denies them.

## COUNT XX

## INFRINGEMENT OF U.S. PATENT NO. 11,649,209 BY MANKIND

593. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

594. Claim 1 of the '209 patent recites:

> 1. A process for preparing a pharmaceutical composition, the process comprising:
>
> dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-l-ylmethyl)benzoyl)]methylamino}-ethyl)piperidin-4-yl ester in a solvent to form a solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Admitted.

595. On information and belief, the manufacture of Mankind's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 595 of the First Amended Consolidated Complaint, and therefore denies them.

596. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Mankind's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '209 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 596 of the First Amended Consolidated Complaint, and therefore denies them.

597. Plaintiffs have requested relevant discovery from Mankind to confirm these characteristics of Mankind's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Mankind's ANDA Product—but have not received said discovery as of the date of this First Amended Complaint. Mankind has an

affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 597 of the First Amended Consolidated Complaint, and therefore denies them.

598. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Mankind's ANDA No. 218089 will constitute acts of infringement of the '209 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 598 of the First Amended Consolidated Complaint, and therefore denies them.

599. On information and belief, Mankind intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, i.e., prior to the expiration of the '209 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 599 of the First Amended Consolidated Complaint, and therefore denies them.

600. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '209 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 600 of the First Amended Consolidated Complaint, and therefore denies them.

601. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 601 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XXI**
**INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY ACCORD**

602. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

603. Accord's submission of ANDA No. 218100 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Accord ANDA Product in/into the United States prior to the expiration of the '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 603 of the First Amended Consolidated Complaint, and therefore denies them.

604. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 604 of the First Amended Consolidated Complaint, and therefore denies them.

605. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 605 of the First Amended Consolidated Complaint, and therefore denies them.

606. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the

proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, i.e., prior to the expiration of the '451 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 606 of the First Amended Consolidated Complaint, and therefore denies them.

607. On information and belief, Accord had knowledge of the '451 patent when it submitted ANDA No. 218100. Accord's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 607 of the First Amended Consolidated Complaint, and therefore denies them.

608. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '451 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 608 of the First Amended Consolidated Complaint, and therefore denies them.

609. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 609 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XXII**
**INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY ACCORD**

610. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

611. Accord's submission of ANDA No. 218100 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Accord ANDA Product in/into the United States prior to the expiration of the '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 611 of the First Amended Consolidated Complaint, and therefore denies them.

612. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 612 of the First Amended Consolidated Complaint, and therefore denies them.

613. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, i.e., prior to the expiration of the '028 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 613 of the First Amended Consolidated Complaint, and therefore denies them.

614. On information and belief, Accord had knowledge of the '028 patent when it submitted ANDA No. 218100. Accord's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 614 of the First Amended Consolidated Complaint, and therefore denies them.

615. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '028 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 615 of the First Amended Consolidated Complaint, and therefore denies them.

616. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 616 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XXIII**
**INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY ACCORD**

617. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

618. Accord's submission of ANDA No. 218100 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Accord ANDA Product in/into the United States prior to the expiration of the '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 618 of the First Amended Consolidated Complaint, and therefore denies them.

619. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 619 of the First Amended Consolidated Complaint, and therefore denies them.

620. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 620 of the First Amended Consolidated Complaint, and therefore denies them.

621. On information and belief, Accord had knowledge of the '081 patent when it submitted ANDA No. 218100. Accord's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 621 of the First Amended Consolidated Complaint, and therefore denies them.

622. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '081 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 622 of the First Amended Consolidated Complaint, and therefore denies them.

623. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 623 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XXIV**
**INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY ACCORD**

624. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

625. Accord's submission of ANDA No. 218100 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Accord ANDA Product in/into the United States prior to the expiration of the '289 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 625 of the First Amended Consolidated Complaint, and therefore denies them.

626. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 626 of the First Amended Consolidated Complaint, and therefore denies them.

627. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, i.e., prior to the expiration of the '289 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 627 of the First Amended Consolidated Complaint, and therefore denies them.

628. On information and belief, Accord had knowledge of the '289 patent when it submitted ANDA No. 218100. Accord's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 628 of the First Amended Consolidated Complaint, and therefore denies them.

629. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '289 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 629 of the First Amended Consolidated Complaint, and therefore denies them.

630. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 630 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XXV**
**INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY ACCORD**

631. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

632. Accord's submission of ANDA No. 218100 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Accord ANDA Product in/into the United States prior to the expiration of the '531 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 632 of the First Amended Consolidated Complaint, and therefore denies them.

633. Unless enjoined, upon FDA approval of Accord's ANDA No. 218100, Accord will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 633 of the First Amended Consolidated Complaint, and therefore denies them.

634. On information and belief, upon FDA approval of Accord's ANDA No. 218100, Accord intends to manufacture, market, sell, and offer to sell Accord's ANDA Product with an FDA-approved package insert that will direct healthcare providers and patients in the use of Accord's ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 634 of the First Amended Consolidated Complaint, and therefore denies them.

635. On information and belief, Accord will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Accord knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '531 patent by marketing Accord's ANDA Product with the FDA-approved package insert.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 635 of the First Amended Consolidated Complaint, and therefore denies them.

636. The '531 patent has one independent claim, claim 1, which states:

> 1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:
>
> (a) selecting a patient having chronic obstructive pulmonary disease
>
> for treatment based on the patient having a peak inspiratory flow rate
>
> less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50 percent; and
>
> (b) administering a pharmaceutical composition comprising about 175 µg of revefenacin, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

**ANSWER:** Admitted.

637. A healthcare provider will directly infringe one of more of the claims of the '531 patent. Specifically, a healthcare provider administering Accord's ANDA Product in accordance with Accord's package insert will perform all of the steps of one or more claims of the '531 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 637 of the First Amended Consolidated Complaint, and therefore denies them.

638. FDA regulations require that approved drug products include prescribing information reciting the FDA-approved indication(s) for the drug and related instructions for healthcare providers to safely and effectively administer the drug. See 21 C.F.R. § 201.56(a)(1)¬(3), (d)(1); 21 C.F.R. § 201.57(a)-(c).

**ANSWER:** Paragraph 638 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 638.

639. Consistent with FDA regulations, the package insert for YUPELRI® includes prescribing information that recites the FDA-approved indication for YUPELRI® and provides instructions for healthcare providers and patients to safely and effectively administer YUPELRI®.

**ANSWER:** Paragraph 639 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 639.

640. The package insert for Accord's ANDA Product will be substantially similar to the package insert for YUPELRI® in all material respects.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 640 of the First Amended Consolidated Complaint, and therefore denies them.

641. Providers of revefenacin review and follow the package inserts for the revefenacin products they use to treat their patients.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 641 of the First Amended Consolidated Complaint, and therefore denies them.

642. On information and belief, Accord is seeking approval to market its ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 642 of the First Amended Consolidated Complaint, and therefore denies them.

643. The YUPELRI® package insert instructs that YUPELRI® is "indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." (Ex. F at § 1).

**ANSWER:** Cipla admits that the YUPELRI® label recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." The remainder of Paragraph 643 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the remaining allegations of Paragraph 643.

644. The "Dosage and Administration" section of the YUPELRI® package instructs that the "recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." (Ex. F at § 2).

**ANSWER:** Cipla admits the YUPELRI ® label recites that "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 644 of the First Amended Consolidated Complaint, and therefore denies them.

645. The "Dosage Form and Strengths" section of the YUPELRI® package insert states that YUPELRI® is an "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." (Ex. F at § 3).

**ANSWER:** Cipla admits that the YUPELRI® label recites "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations containing in Paragraph 645 of the First Amended Consolidated Complaint, and therefore denies them.

646. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 646 of the First Amended Consolidated Complaint, and therefore denies them.

647. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 647 of the First Amended Consolidated Complaint, and therefore denies them.

648. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV1 of 55%. (Id.)

**ANSWER:** Cipla admits that the YUPELRI® label recites "[a]t screening, the mean post-bronchodilator percent predicted FEV1 was 55% (range: 10% to 90%), and the post-broncodilator FEV1/FVC ratio was 0.54 (range: 0.3 to 0.7)." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 648 of the First Amended Consolidated Complaint, and therefore denies them.

649. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV1 of equal to or greater than 30% and less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 649 of the First Amended Consolidated Complaint, and therefore denies them.

650. A healthcare provider, or a patient at the direction of a healthcare provider, will administer Accord's ANDA Product to the patient once daily using a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 650 of the First Amended Consolidated Complaint, and therefore denies them.

651. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

**ANSWER:** Cipla admits that the YUPELRI® label recites "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 651 of the First Amended Consolidated Complaint, and therefore denies them.

652. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient's ability to use an inhaler.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 652 of the First Amended Consolidated Complaint, and therefore denies them.

653. It is known that successful use of dry powder inhalers such as the HandiHaler® requires a PIFR of 60 L/min.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 653 of the First Amended Consolidated Complaint, and therefore denies them.

654. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. See, e.g., Mahler 2017; Mahler 2014.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 654 of the First Amended Consolidated Complaint, and therefore denies them.

655. On information and belief, Accord specifically intends that its ANDA product, if marketed, would be administered to some patients with moderate to severe COPD having a PIFR of less than about 60 L/min and FEV1 of less than 50%, using a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 655 of the First Amended Consolidated Complaint, and therefore denies them.

656. On information and belief, Accord knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 656 of the First Amended Consolidated Complaint, and therefore denies them.

657. On information and belief, Accord knows, and specifically intends, that some healthcare providers will select patients for treatment with its proposed ANDA product, if marketed, based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 657 of the First Amended Consolidated Complaint, and therefore denies them.

658. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '531 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 658 of the First Amended Consolidated Complaint, and therefore denies them.

659. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 659 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XXVI**
**INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY ACCORD**

660. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

661. Accord's submission of ANDA No. 218100 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Accord ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 661 of the First Amended Consolidated Complaint, and therefore denies them.

662. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 662 of the First Amended Consolidated Complaint, and therefore denies them.

663. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 663 of the First Amended Consolidated Complaint, and therefore denies them.

664. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the

proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, i.e., prior to the expiration of the '948 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 664 of the First Amended Consolidated Complaint, and therefore denies them.

665. On information and belief, Accord had knowledge of the '948 patent when it submitted the Accord '948 Patent Paragraph IV Certification as part of ANDA No. 218100. Accord's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 665 of the First Amended Consolidated Complaint, and therefore denies them.

666. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '948 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 666 of the First Amended Consolidated Complaint, and therefore denies them.

667. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 667 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XXVII**
**INFRINGEMENT OF U.S. PATENT NO. 8,017,783 BY ACCORD**

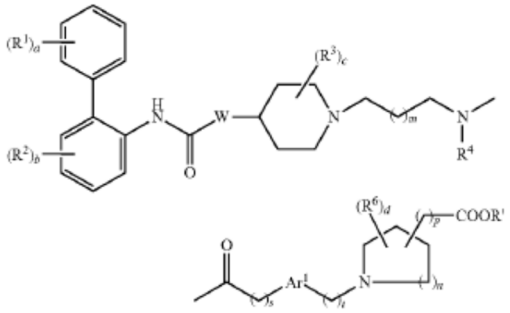
668. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

669. Claim 1 of the '783 patent recites:

1. A compound of formula XVIII:

XVIII



wherein:

a is 0 or an integer of from 1 to 5;

each $R^1$ is independently selected from (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (3-6C)cycloalkyl, cyano, halo, —$OR^{1a}$, —$C(O)OR^{1b}$, —$SR^{1c}$, —$S(O)R^{1d}$, —$S(O)_2R^{1e}$, —$NR^{1f}R^{1g}$, —$NR^{1h}S(O)_2R^{1i}$, and —$NR^{1j}C(O)R^{1k}$; where each of $R^{1a}$, $R^{1b}$, $R^{1c}$, $R^{1d}$, $R^{1e}$, $R^{1f}$, $R^{1g}$, $R^{1h}$, $R^{1i}$, $R^{1j}$, and $R^{1k}$ is independently hydrogen, (1-4C)alkyl or phenyl(1-4C)alkyl;

b is 0 or an integer of from 1 to 4;

each $R^2$ is independently selected from (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (3-6C)cycloalkyl, cyano, halo, —$OR^{2a}$, —$C(O)OR^{2b}$, —$SR^{2c}$, —$S(O)R^{2d}$, —$S(O)_2R^{2e}$, —$NR^{2f}R^{2g}$, —$NR^{2h}S(O)_2R^{2i}$, and —$NR^{2j}C(O)R^{2k}$; where each of $R^{2a}$, $R^{2b}$, $R^{2c}$, $R^{2d}$, $R^{2e}$, $R^{2f}$, $R^{2g}$, $R^{2h}$, $R^{2i}$, $R^{2j}$, and $R^{2k}$ is independently hydrogen, (1-4C)alkyl or phenyl(1-4C)alkyl;

W represents O or $NW^a$, where $W^a$ is hydrogen or (1-4C)alkyl;

c is 0 or an integer from 1 to 5;

each $R^3$ independently represents (1-4C)alkyl or two $R^3$ groups are joined to form (1-3C)alkylene, (2-3C)alkenylene or oxiran-2,3-diyl;

m is 0 or 1;

$R^4$ is selected from hydrogen, (1-4C)alkyl, and (3-4C)cycloalkyl;

s is 0, 1 or 2;

$Ar^1$ represents a phenylene group or a (3-5C)heteroarylene group containing 1 or 2 heteroatoms independently selected from oxygen, nitrogen, and sulfur; wherein the phenylene or heteroarylene group is substituted with $(R^5)_q$ where q is 0 or an integer from 1 to 4 and each $R^5$ is independently selected from halo, hydroxy, (1-4C)alkyl, and (1-4C)alkoxy;

t is 0, 1 or 2;

n is 0 or an integer from 1 to 3;

d is 0 or an integer from 1 to 4;

each $R^6$ independently represents fluoro or (1-4C)alkyl;

p is 0 or 1; and

R' is selected from hydrogen, —$CH_3$, and —$CH_2CH_3$;

wherein each alkyl and alkoxy group in $R^1$, $R^{1a\text{-}1k}$, $R^2$, $R^{2a\text{-}2k}$, $R^3$, $R^5$, and $R^6$ is optionally substituted with 1 to 5 fluoro substituents;

or a pharmaceutically acceptable salt or stereoisomer thereof.

**ANSWER:** Admitted.

670. According to the YUPELRI® package insert, in Section 12.3, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 670 of the First Amended Consolidated Complaint, and therefore denies them.

671. According to the YUPELRI® package insert, in Section 12.3, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly[.]" Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 671 of the First Amended Consolidated Complaint, and therefore denies them.

672. On information and belief, when a patient uses the Accord ANDA Product, the revefenacin contained in the Accord ANDA Product will undergo hydrolysis of the primary amide to form a carboxcylic acid.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 672 of the First Amended Consolidated Complaint, and therefore denies them.

673. On information and belief, the compound resulting from that reaction is a compound within the scope of Claim 1 of the '783 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 673 of the First Amended Consolidated Complaint, and therefore denies them.

674. The commercial use of the product that is the subject of Accord's ANDA No. 218100 will constitute an act of infringement of the '783 patent under 35 U.S.C. § 271(b) and (c) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 674 of the First Amended Consolidated Complaint, and therefore denies them.

675. On information and belief, Accord intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, i.e., prior to the expiration of the '783 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 675 of the First Amended Consolidated Complaint, and therefore denies them.

676. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '783 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 676 of the First Amended Consolidated Complaint, and therefore denies them.

677. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 677 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XXVIII**

**INFRINGEMENT OF U.S. PATENT NO. 9,249,099 BY ACCORD**

678. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

679. Claim 1 of the '099 patent recites:

> 1. A crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1 ylmethyl)benzoyl]methylamino}ethyl)piperidin-4-yl ester, characterized by a powder x-ray diffraction pattern having:
>
> (a) two or more diffraction peaks at 2θ values selected from 4.7±0.2, 9.6±0.2, 12.7±0.2, 13.7±0.2, 16.7±0.2, 17.4±0.2, 18.5±0.2, 19.4±0.2, 20.8±0.2, 21.4±0.2, 24.2±0.2, and 25.6±0.2; or
>
> (b) two or more diffraction peaks at 2θ values selected from 4.6±0.2, 9.3±0.2, 12.9±0.2, 13.6±0.2, 14.0±0.2, 14.6±0.2, 16.5±0.2, 18.6±0.2, 19.1±0.2, 20.9±0.2, 22.1±0.2, 22.7±0.2, and 25.7±0.2.

**ANSWER:** Admitted.

680. On information and belief, Accord uses some amount of a compound recited in claim 1 of the '099 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 680 of the First Amended Consolidated Complaint, and therefore denies them.

681. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Accord's ANDA No. 218100 will constitute acts of infringement of the '099 patent under 35 U.S.C. §§ 271(a) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 681 of the First Amended Consolidated Complaint, and therefore denies them.

682. On information and belief, Accord intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon

the approval of ANDA No. 218100 and any amendments thereto, i.e., prior to the expiration of the '099 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 682 of the First Amended Consolidated Complaint, and therefore denies them.

683. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '099 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 683 of the First Amended Consolidated Complaint, and therefore denies them.

684. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 684 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XXIX**
**INFRINGEMENT OF U.S. PATENT NO. 10,100,013 BY ACCORD**

685. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

686. Claim 1 of the '013 patent recites:

> 1. A method for preparing a pharmaceutical composition for use in a nebulizer inhaler, the method comprising dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}
>
> ethyl)piperidin-4-yl ester in an aqueous pharmaceutical carrier to form an aqueous solution; wherein the crystalline freebase is characterized by a powder x-ray

diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Admitted.

687. On information and belief, the manufacture of Accord's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 687 of the First Amended Consolidated Complaint, and therefore denies them.

688. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Accord's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '013 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 688 of the First Amended Consolidated Complaint, and therefore denies them.

689. Plaintiffs have requested relevant discovery from Accord to confirm these characteristics of Accord's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Accord's ANDA Product—but have not received said discovery as of the date of this First Amended Complaint. Accord has an affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 689 of the First Amended Consolidated Complaint, and therefore denies them.

690. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Accord's ANDA No. 218100 will constitute acts of infringement of the '013 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 690 of the First Amended Consolidated Complaint, and therefore denies them.

691. On information and belief, Accord intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, i.e., prior to the expiration of the '013 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 691 of the First Amended Consolidated Complaint, and therefore denies them.

692. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '013 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 692 of the First Amended Consolidated Complaint, and therefore denies them.

693. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 693 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XXX**
**INFRINGEMENT OF U.S. PATENT NO. 11,649,209 BY ACCORD**

694. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

695. Claim 1 of the '209 patent recites:

> 1. A process for preparing a pharmaceutical composition, the process comprising:
>
> dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-l-ylmethyl)benzoyl)]methylamino}-ethyl)piperidin-4-yl ester in a solvent to form a solution; wherein the crystalline freebase is characterized by

a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Admitted.

696. On information and belief, the manufacture of Accord's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 696 of the First Amended Consolidated Complaint, and therefore denies them.

697. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Accord's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '209 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 697 of the First Amended Consolidated Complaint, and therefore denies them.

698. Plaintiffs have requested relevant discovery from Accord to confirm these characteristics of Accord's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Accord's ANDA Product—but have not received said discovery as of the date of this First Amended Complaint. Accord has an affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 698 of the First Amended Consolidated Complaint, and therefore denies them.

699. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Accord's ANDA No. 218100 will constitute acts of infringement of the '209 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 699 of the First Amended Consolidated Complaint, and therefore denies them.

700. On information and belief, Accord intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, i.e., prior to the expiration of the '209 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 700 of the First Amended Consolidated Complaint, and therefore denies them.

701. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '209 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 701 of the First Amended Consolidated Complaint, and therefore denies them.

702. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 702 of the First Amended Consolidated Complaint, and therefore denies them.

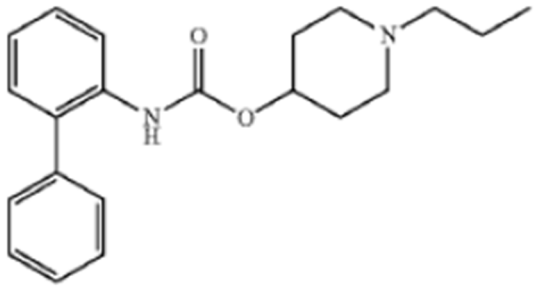
**COUNT XXXI**
**INFRINGEMENT OF U.S. PATENT NO. 8,754,225 BY ACCORD**

703. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

704. Claim 1 of the '225 patent recites:

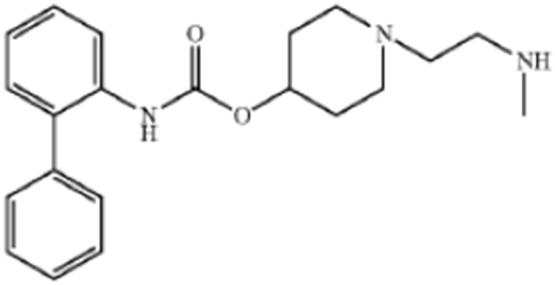
1. A process for preparing a crystalline freebase (Form III) of the compound of formula I:



(I)

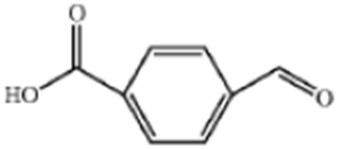
the process comprising the steps of:

(a) coupling a compound of formula 8:



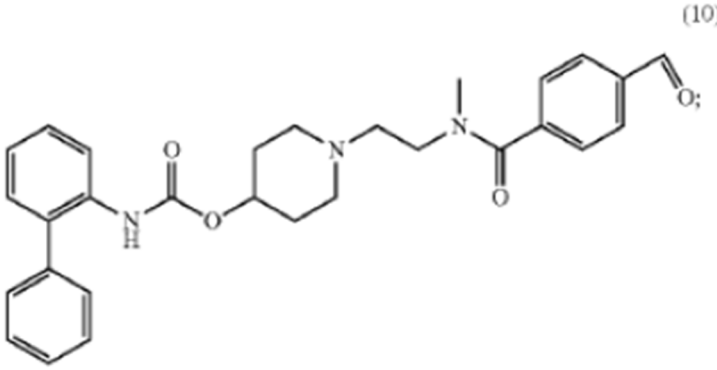
(8)

with a compound of formula 9:



(9)

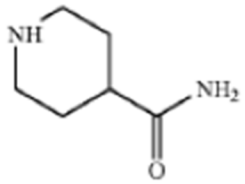
in the presence of a coupling reagent to yield the compound of formula 10:



(10)

(b) reductive amination of the compound of formula 10 and a compound of formula 11:

(11)




in the presence of a reducing agent to yield the compound of formula I, wherein azeotropic distillation of water is conducted at an elevated temperature prior to the addition of the reducing agent, and reductive amination is conducted at room temperature;

(c) contacting the product of step (b) with isopropyl acetate, optionally adding a seed crystal of the crystalline freebase (Form III) to form a solid, and isolating the resulting solid; and

(d) contacting the product of step (c) with toluene, optionally adding a seed crystal of the crystalline freebase (Form III) to form a solid, and isolating the resulting solid as the crystalline freebase (Form III) wherein step (a) and step (b) are conducted in the same reaction mixture without isolation of the intermediate from step (a)

**ANSWER:** Admitted.

705. On information and belief, the manufacture of Accord's ANDA Product involves the steps disclosed in claim 1 of the '225 patent or equivalents thereof.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 705 of the First Amended Consolidated Complaint, and therefore denies them.

706. Plaintiffs have requested relevant discovery from Accord to confirm the process by which Accord's ANDA Product is prepared—in particular, a complete copy of the closed DMF—but Accord has refused to permit Plaintiffs access to such discovery for the purpose of assessing infringement, including with respect to the '225 patent. Pursuant to 35 U.S.C. § 295, however, Accord's ANDA Product is presumed to have been made by the process described in claim 1 of the '225 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 706 of the First Amended Consolidated Complaint, and therefore denies them.

707. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Accord's ANDA No. 218100 will constitute acts of infringement of the '225 patent under 35 U.S.C. §§ 271(a) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 707 of the First Amended Consolidated Complaint, and therefore denies them.

708. On information and belief, Accord intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, i.e., prior to the expiration of the '225 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 708 of the First Amended Consolidated Complaint, and therefore denies them.

709. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '225 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 709 of the First Amended Consolidated Complaint, and therefore denies them.

710. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 710 of the First Amended Consolidated Complaint, and therefore denies them.

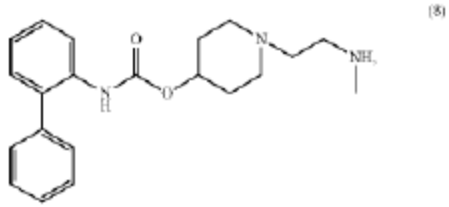
**COUNT XXXII**
**INFRINGEMENT OF U.S. PATENT NO. 9,035,061 BY ACCORD**

711. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

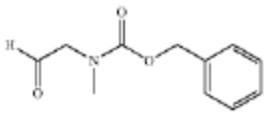
712. Claim 1 of the '061 patent recites:

1. A process for preparing a compound of formula 8:



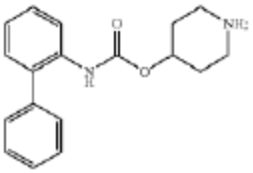
(8)

the process comprising the steps of:
(a) reductive amination of a compound of formula 3:



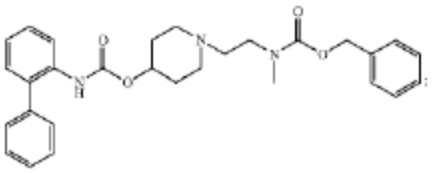
(3)

and a compound of formula 6:



(6)

in the presence of a reducing agent, to yield the compound of formula 7:



(7)

and
(b) debenzylation of the compound of formula 7 to yield the compound of formula 8; wherein step (a) and step (b)

are conducted in the same reaction mixture without isolation of the intermediate from step (a); wherein steps (a) and (b) are conducted in methyltetrahydrofuran.

**ANSWER:** Admitted.

713. On information and belief, the manufacture of Accord's ANDA Product involves the steps disclosed in claim 1 of the '061 patent or equivalents thereof.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 713 of the First Amended Consolidated Complaint, and therefore denies them.

714. Plaintiffs have requested relevant discovery from Accord to confirm the process by which Accord's ANDA Product is prepared—in particular, a complete copy of the closed DMF—but Accord has refused to permit Plaintiffs access to such discovery for the purpose of assessing infringement, including with respect to the '061 patent. Pursuant to 35 U.S.C. § 295, however, Accord's ANDA Product is presumed to have been made by the process described in claim 1 of the '061 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 714 of the First Amended Consolidated Complaint, and therefore denies them.

715. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Accord's ANDA No. 218100 will constitute acts of infringement of the '061 patent under 35 U.S.C. §§ 271(a) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 715 of the First Amended Consolidated Complaint, and therefore denies them.

716. On information and belief, Accord intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, i.e., prior to the expiration of the '061 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 716 of the First Amended Consolidated Complaint, and therefore denies them.

717. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '061 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 717 of the First Amended Consolidated Complaint, and therefore denies them.

718. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 718 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNTS XXXIII-XLIV**
**BY MEDICHEM**

719. - 835. *[REDACTED IN SERVICE COPY TO CIPLA]*

**ANSWER:** Because Paragraphs 719-835 were sealed and redacted from the service copy of the First Amended Consolidated Complaint which Cipla received, Cipla deems that no answer to those paragraphs is necessary. To the extent such answer is required, Cipla denies Paragraphs 719-835.

**COUNT XLV**
**INFRINGEMENT OF U.S. PATENT NO. 8,541.451 BY LUPIN**

836. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

837. Lupin's submission of ANDA No. 218088 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Lupin ANDA Product in/into the United States prior to the expiration of the '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 837 of the First Amended Consolidated Complaint, and therefore denies them.

838. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 838 of the First Amended Consolidated Complaint, and therefore denies them.

839. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 839 of the First Amended Consolidated Complaint, and therefore denies them.

840. On information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, *i.e.*, prior to the expiration of the '451 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 840 of the First Amended Consolidated Complaint, and therefore denies them.

841. On information and belief, Lupin had knowledge of the '451 patent when it submitted ANDA No. 218088. Lupin's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 841 of the First Amended Consolidated Complaint, and therefore denies them.

842. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '451 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 842 of the First Amended Consolidated Complaint, and therefore denies them.

843. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 843 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XLVI**
**INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY LUPIN**

844. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

845. Lupin's submission of ANDA No. 218088 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Lupin ANDA Product in/into the United States prior to the expiration of the '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 845 of the First Amended Consolidated Complaint, and therefore denies them.

846. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 846 of the First Amended Consolidated Complaint, and therefore denies them.

847. On information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, i.e., prior to the expiration of the '028 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 847 of the First Amended Consolidated Complaint, and therefore denies them.

848. On information and belief, Lupin had knowledge of the '028 patent when it submitted ANDA No. 218088. Lupin Inc.'s infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 848 of the First Amended Consolidated Complaint, and therefore denies them.

849. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '028 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 849 of the First Amended Consolidated Complaint, and therefore denies them.

850. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 850 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XLVII**
**INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY LUPIN**

851. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

852. Lupin's submission of ANDA No. 218088 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Lupin ANDA Product in/into the United States prior to the expiration of the '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 852 of the First Amended Consolidated Complaint, and therefore denies them.

853. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 853 of the First Amended Consolidated Complaint, and therefore denies them.

854. On information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, i.e., prior to the expiration of the '081 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 854 of the First Amended Consolidated Complaint, and therefore denies them.

855. On information and belief, Lupin had knowledge of the '081 patent when it submitted ANDA No. 218088. Lupin's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 855 of the First Amended Consolidated Complaint, and therefore denies them.

856. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '081 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 856 of the First Amended Consolidated Complaint, and therefore denies them.

857. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 857 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XLVIII**
**INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY LUPIN**

858. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

859. Lupin's submission of ANDA No. 218088 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Lupin ANDA Product in/into the United States prior to the expiration of the '289 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 859 of the First Amended Consolidated Complaint, and therefore denies them.

860. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 860 of the First Amended Consolidated Complaint, and therefore denies them.

861. On information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, i.e., prior to the expiration of the '289 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 861 of the First Amended Consolidated Complaint, and therefore denies them.

862. On information and belief, Lupin had knowledge of the '289 patent when it submitted ANDA No. 218088. Lupin's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 862 of the First Amended Consolidated Complaint, and therefore denies them.

863. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '289 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 863 of the First Amended Consolidated Complaint, and therefore denies them.

864. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 864 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT XLIX**
**INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY LUPIN**

865. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

866. Lupin's submission of ANDA No. 218088 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Lupin ANDA Product in/into the United States prior to the expiration of the '531 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 866 of the First Amended Consolidated Complaint, and therefore denies them.

867. Unless enjoined, upon FDA approval of Lupin's ANDA No. 218088, Lupin will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 867 of the First Amended Consolidated Complaint, and therefore denies them.

868. On information and belief, upon FDA approval of Lupin's ANDA No. 218088, Lupin intends to manufacture, market, sell, and offer to sell Lupin's ANDA Product with an FDA-approved package insert that will direct healthcare providers and patients in the use of Lupin's ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 868 of the First Amended Consolidated Complaint, and therefore denies them.

869. On information and belief, Lupin will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Lupin knows will directly infringe,

either literally or under the doctrine of equivalents, one or more claims of the '531 patent by marketing Lupin's ANDA Product with the FDA-approved package insert.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 869 of the First Amended Consolidated Complaint, and therefore denies them.

870. The '531 patent has one independent claim, claim 1, which states:

> 1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:
>
> (a) selecting a patient having chronic obstructive pulmonary disease for treatment based on the patient having a peak inspiratory flow rate less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50 percent; and
>
> (b) administering a pharmaceutical composition comprising about 175 µg of revefenacin, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

**ANSWER:** Admitted.

871. A healthcare provider will directly infringe one of more of the claims of the '531 patent. Specifically, a healthcare provider administering Lupin's ANDA Product in accordance with Lupin's package insert will perform all of the steps of one or more claims of the '531 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 871 of the First Amended Consolidated Complaint, and therefore denies them.

872 FDA regulations require that approved drug products include prescribing information reciting the FDA-approved indication(s) for the drug and related instructions for healthcare providers to safely and effectively administer the drug. See 21 C.F.R. § 201.56(a)(1)¬(3), (d)(1); 21 C.F.R. § 201.57(a)-(c).

**ANSWER:** Paragraph 872 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 872.

873. Consistent with FDA regulations, the package insert for YUPELRI® includes prescribing information that recites the FDA-approved indication for YUPELRI® and provides instructions for healthcare providers and patients to safely and effectively administer YUPELRI®.

**ANSWER:** Paragraph 873 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 873.

874. The package insert for Lupin's ANDA Product will be substantially similar to the package insert for YUPELRI® in all material respects.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 874 of the First Amended Consolidated Complaint, and therefore denies them.

875. Providers of revefenacin review and follow the package inserts for the revefenacin products they use to treat their patients.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 875 of the First Amended Consolidated Complaint, and therefore denies them.

876. On information and belief, Lupin is seeking approval to market its ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 876 of the First Amended Consolidated Complaint, and therefore denies them.

877. The YUPELRI® package insert instructs that YUPELRI® is "indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." (Ex. F at § 1).

**ANSWER:** Cipla admits that the YUPELRI® label recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)."

The remainder of Paragraph 877 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the remaining allegations of Paragraph 877.

878. The "Dosage and Administration" section of the YUPELRI® package instructs that the "recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." (Ex. F at § 2).

**ANSWER:** Cipla admits the YUPELRI ® label recites that "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 878 of the First Amended Consolidated Complaint, and therefore denies them.

879. The "Dosage Form and Strengths" section of the YUPELRI® package insert states that YUPELRI® is an "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." (Ex. F at § 3).

**ANSWER:** Cipla admits that the YUPELRI® label recites "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations containing in Paragraph 879 of the First Amended Consolidated Complaint, and therefore denies them.

880. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 880 of the First Amended Consolidated Complaint, and therefore denies them.

881. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

**ANSWER:**

882. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV1 of 55%. (Id.)

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 882 of the First Amended Consolidated Complaint, and therefore denies them.

883. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV1 of equal to or greater than 30% and less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 883 of the First Amended Consolidated Complaint, and therefore denies them.

884. A healthcare provider, or a patient at the direction of a healthcare provider, will administer Lupin's ANDA Product to the patient once daily using a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 884 of the First Amended Consolidated Complaint, and therefore denies them.

885. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

**ANSWER:** Cipla admits that the YUPELRI® label recites "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 885 of the First Amended Consolidated Complaint, and therefore denies them.

886. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient's ability to use an inhaler.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 886 of the First Amended Consolidated Complaint, and therefore denies them.

887. It is known that successful use of dry powder inhalers such as the HandiHaler® requires a PIFR of 60 L/min.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 887 of the First Amended Consolidated Complaint, and therefore denies them.

888. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. See, e.g., Mahler 2017; Mahler 2014.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 888 of the First Amended Consolidated Complaint, and therefore denies them.

889. On information and belief, Lupin specifically intends that its ANDA product, if marketed, would be administered to some patients with moderate to severe COPD having a PIFR of less than about 60 L/min and FEV1 of less than 50%, using a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 889 of the First Amended Consolidated Complaint, and therefore denies them.

890. On information and belief, Lupin knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 890 of the First Amended Consolidated Complaint, and therefore denies them.

891. On information and belief, Lupin knows, and specifically intends, that some healthcare providers will select patients for treatment with its proposed ANDA product, if

marketed, based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 891 of the First Amended Consolidated Complaint, and therefore denies them.

892. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '531 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 892 of the First Amended Consolidated Complaint, and therefore denies them.

893. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 893 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT L**
**INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY LUPIN**

894. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

895. Lupin's submission of ANDA No. 218088 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Lupin ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 895 of the First Amended Consolidated Complaint, and therefore denies them.

896. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 896 of the First Amended Consolidated Complaint, and therefore denies them.

897. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 897 of the First Amended Consolidated Complaint, and therefore denies them.

898. On information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, *i.e.*, prior to the expiration of the '948 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 898 of the First Amended Consolidated Complaint, and therefore denies them.

899. On information and belief, Lupin had knowledge of the '948 patent when it submitted the Lupin '948 Patent Paragraph IV Certification as part of ANDA No. 218088. Lupin's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 899 of the First Amended Consolidated Complaint, and therefore denies them.

900. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '948 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 900 of the First Amended Consolidated Complaint, and therefore denies them.

901. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 901 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LI**
**INFRINGEMENT OF U.S. PATENT NO. 8,017,783 BY LUPIN**

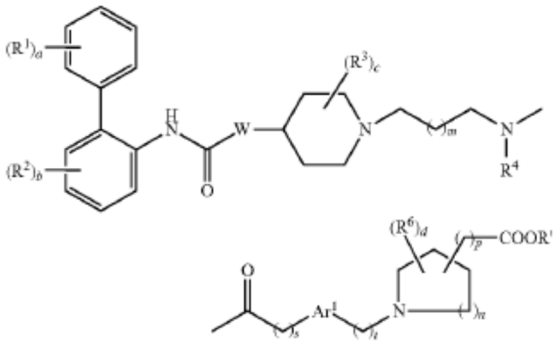
902. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

903. Claim 1 of the '783 patent recites:

1. A compound of formula XVIII:

XVIII



wherein:

a is 0 or an integer of from 1 to 5;

each $R^1$ is independently selected from (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (3-6C)cycloalkyl, cyano, halo, —$OR^{1a}$, $C(O)OR^{1b}$, —$SR^{1c}$, —$S(O)R^{1d}$, —$S(O)_2R^{1e}$, —$NR^{1f}R^{1g}$, —$NR^{1h}S(O)_2R^{1i}$, and —$NR^{1j}C(O)R^{1k}$; where each of $R^{1a}$, $R^{1b}$, $R^{1c}$, $R^{1d}$, $R^{1e}$, $R^{1f}$, $R^{1g}$, $R^{1h}$, $R^{1i}$, $R^{1j}$, and $R^{1k}$ is independently hydrogen, (1-4C)alkyl or phenyl(1-4C)alkyl;

b is 0 or an integer of from 1 to 4;

each $R^2$ is independently selected from (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (3-6C)cycloalkyl, cyano, halo, —$OR^{2a}$, —$C(O)OR^{2b}$, —$SR^{2c}$, —$S(O)R^{2d}$, —$S(O)_2R^{2e}$, —$NR^{2f}R^{2g}$, —$NR^{2h}S(O)_2R^{2i}$, and —$NR^{2j}C(O)R^{2k}$; where each of $R^{2a}$, $R^{2b}$, $R^{2c}$, $R^{2d}$, $R^{2e}$, $R^{2f}$, $R^{2g}$, $R^{2h}$, $R^{2i}$, $R^{2j}$, and $R^{2k}$ is independently hydrogen, (1-4C)alkyl or phenyl(1-4C)alkyl;

W represents O or $NW^a$, where $W^a$ is hydrogen or (1-4C)alkyl;

c is 0 or an integer from 1 to 5;

each $R^3$ independently represents (1-4C)alkyl or two $R^3$ groups are joined to form (1-3C)alkylene, (2-3C)alkenylene or oxiran-2,3-diyl;

m is 0 or 1;

$R^4$ is selected from hydrogen, (1-4C)alkyl, and (3-4C)cycloalkyl;

s is 0, 1 or 2;

$Ar^1$ represents a phenylene group or a (3-5C)heteroarylene group containing 1 or 2 heteroatoms independently selected from oxygen, nitrogen, and sulfur; wherein the phenylene or heteroarylene group is substituted with $(R^5)_q$ where q is 0 or an integer from 1 to 4 and each $R^5$ is independently selected from halo, hydroxy, (1-4C)alkyl, and (1-4C)alkoxy;

t is 0, 1 or 2;

n is 0 or an integer from 1 to 3;

d is 0 or an integer from 1 to 4;

each $R^6$ independently represents fluoro or (1-4C)alkyl;

p is 0 or 1; and

R' is selected from hydrogen, —$CH_3$, and —$CH_2CH_3$;

wherein each alkyl and alkoxy group in $R^1$, $R^{1a-1k}$, $R^2$, $R^{2a-2k}$, $R^3$, $R^5$, and $R^6$ is optionally substituted with 1 to 5 fluoro substituents;

or a pharmaceutically acceptable salt or stereoisomer thereof.

**ANSWER:** Admitted.

904. According to the YUPELRI® package insert, in Section 12.3, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 904 of the First Amended Consolidated Complaint, and therefore denies them.

905. According to the YUPELRI® package insert, in Section 12.3, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly[.]" Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 905 of the First Amended Consolidated Complaint, and therefore denies them.

906. On information and belief, when a patient uses the Lupin ANDA Product, the revefenacin contained in the Lupin ANDA Product will undergo hydrolysis of the primary amide to form a carboxcylic acid.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 906 of the First Amended Consolidated Complaint, and therefore denies them.

907. On information and belief, the compound resulting from that reaction is a compound within the scope of Claim 1 of the '783 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 907 of the First Amended Consolidated Complaint, and therefore denies them.

908. The commercial use of the product that is the subject of Lupin's ANDA No. 218088 will constitute an act of infringement of the '783 patent under 35 U.S.C. § 271(b) and (c) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 908 of the First Amended Consolidated Complaint, and therefore denies them.

909. On information and belief, Lupin intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, *i.e.*, prior to the expiration of the '783 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 909 of the First Amended Consolidated Complaint, and therefore denies them.

910. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '783 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 910 of the First Amended Consolidated Complaint, and therefore denies them.

911. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 911 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LII**

**INFRINGEMENT OF U.S. PATENT NO. 9,249,099 BY LUPIN**

912. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

913. Claim 1 of the '099 patent recites:

> 1. A crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1
>
> ylmethyl)benzoyl]methylamino}ethyl)piperidin-4-yl ester, characterized by a powder x-ray diffraction pattern having:
>
> (a) two or more diffraction peaks at 2θ values selected from 4.7±0.2, 9.6±0.2, 12.7±0.2, 13.7±0.2, 16.7±0.2, 17.4±0.2, 18.5±0.2, 19.4±0.2, 20.8±0.2, 21.4±0.2, 24.2±0.2, and 25.6±0.2; or
>
> (b) two or more diffraction peaks at 2θ values selected from 4.6±0.2, 9.3±0.2, 12.9±0.2, 13.6±0.2, 14.0±0.2, 14.6±0.2, 16.5±0.2, 18.6±0.2, 19.1±0.2, 20.9±0.2, 22.1±0.2, 22.7±0.2, and 25.7±0.2.

**ANSWER:** Admitted.

914. On information and belief, Lupin uses some amount of a compound recited in claim 1 of the '099 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 914 of the First Amended Consolidated Complaint, and therefore denies them.

915. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Lupin's ANDA No. 218088 will constitute acts of infringement of the '099 patent under 35 U.S.C. §§ 271(a) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 915 of the First Amended Consolidated Complaint, and therefore denies them.

916. On information and belief, Lupin intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, *i.e.*, prior to the expiration of the '099 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 916 of the First Amended Consolidated Complaint, and therefore denies them.

917. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '099 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 917 of the First Amended Consolidated Complaint, and therefore denies them.

918. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 918 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LIII**
**INFRINGEMENT OF U.S. PATENT NO. 10,100,013 BY LUPIN**

919. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

920. Claim 1 of the '013 patent recites:

> 1. A method for preparing a pharmaceutical composition for use in a nebulizer inhaler, the method comprising dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}

ethyl)piperidin-4-yl ester in an aqueous pharmaceutical carrier to form an aqueous solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Admitted.

921. On information and belief, the manufacture of Lupin's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 921 of the First Amended Consolidated Complaint, and therefore denies them.

922. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Lupin's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '013 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 922 of the First Amended Consolidated Complaint, and therefore denies them.

923. Plaintiffs have requested relevant discovery from Lupin to confirm these characteristics of Lupin's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Lupin's ANDA Product—but have not received said discovery as of the date of this First Amended Complaint. Lupin has an affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 923 of the First Amended Consolidated Complaint, and therefore denies them.

924. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Lupin's ANDA No. 218088 will constitute acts of infringement of the '013 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 924 of the First Amended Consolidated Complaint, and therefore denies them.

925. On information and belief, Lupin intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, *i.e.*, prior to the expiration of the '013 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 925 of the First Amended Consolidated Complaint, and therefore denies them.

926. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '013 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 926 of the First Amended Consolidated Complaint, and therefore denies them.

927. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 927 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LIV**
**INFRINGEMENT OF U.S. PATENT NO. 11,649,209 BY LUPIN**

928. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

929. Claim 1 of the '209 patent recites:

> 1. A process for preparing a pharmaceutical composition, the process comprising:
>
> dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-l-ylmethyl)benzoyl)]methylamino}-ethyl)piperidin-4-yl ester in a solvent to form a solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Admitted.

930. On information and belief, the manufacture of Lupin's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 930 of the First Amended Consolidated Complaint, and therefore denies them.

931. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Lupin's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '209 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 931 of the First Amended Consolidated Complaint, and therefore denies them.

932. Plaintiffs have requested relevant discovery from Lupin to confirm these characteristics of Lupin's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Lupin's ANDA Product—but have not received said discovery as of the date of this First Amended Complaint. Lupin has an affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 932 of the First Amended Consolidated Complaint, and therefore denies them.

933. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Lupin's ANDA No. 218088 will constitute acts of infringement of the '209 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 933 of the First Amended Consolidated Complaint, and therefore denies them.

934. On information and belief, Lupin intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, *i.e.*, prior to the expiration of the '209 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 934 of the First Amended Consolidated Complaint, and therefore denies them.

935. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '209 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 935 of the First Amended Consolidated Complaint, and therefore denies them.

936. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 936 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LV**
**INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY ORBICULAR**

937. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

938. Orbicular's submission of ANDA No. 217868 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Orbicular ANDA Product in/into the United States prior to the expiration of the '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 938 of the First Amended Consolidated Complaint, and therefore denies them.

939. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 939 of the First Amended Consolidated Complaint, and therefore denies them.

940. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 940 of the First Amended Consolidated Complaint, and therefore denies them.

941. On information and belief, Orbicular intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, *i.e.*, prior to the expiration of the '451 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 941 of the First Amended Consolidated Complaint, and therefore denies them.

942. On information and belief, Orbicular had knowledge of the '451 patent when it submitted ANDA No. 217868. Orbicular's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 942 of the First Amended Consolidated Complaint, and therefore denies them.

943. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '451 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 943 of the First Amended Consolidated Complaint, and therefore denies them.

944. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 944 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LVI**
**INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY ORBICULAR**

945. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

946. Orbicular's submission of ANDA No. 217868 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Orbicular ANDA Product in/into the United States prior to the expiration of the '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 946 of the First Amended Consolidated Complaint, and therefore denies them.

947. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 947 of the First Amended Consolidated Complaint, and therefore denies them.

948. On information and belief, Orbicular intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, *i.e.*, prior to the expiration of the '028 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 948 of the First Amended Consolidated Complaint, and therefore denies them.

949. On information and belief, Orbicular had knowledge of the '028 patent when it submitted ANDA No. 217868. Orbicular's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 949 of the First Amended Consolidated Complaint, and therefore denies them.

950. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '028 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 950 of the First Amended Consolidated Complaint, and therefore denies them.

951. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 951 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LVII**
**INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY ORBICULAR**

952. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

953. Orbicular's submission of ANDA No. 217868 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Orbicular ANDA Product in/into the United States prior to the expiration of the '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 953 of the First Amended Consolidated Complaint, and therefore denies them.

954. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 954 of the First Amended Consolidated Complaint, and therefore denies them.

955. On information and belief, Orbicular intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 955 of the First Amended Consolidated Complaint, and therefore denies them.

956. On information and belief, Orbicular had knowledge of the '081 patent when it submitted ANDA No. 217868. Orbicular's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 956 of the First Amended Consolidated Complaint, and therefore denies them.

957. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '081 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 957 of the First Amended Consolidated Complaint, and therefore denies them.

958. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 958 of the First Amended Consolidated Complaint, and therefore denies them.

## COUNT LVIII
## INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY ORBICULAR

959. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

960. Orbicular's submission of ANDA No. 217868 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Orbicular ANDA Product in/into the United States prior to the expiration of the '289 patent constitutes infringement, either literally or under

the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 960 of the First Amended Consolidated Complaint, and therefore denies them.

961. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 961 of the First Amended Consolidated Complaint, and therefore denies them.

962. On information and belief, Orbicular intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, *i.e.*, prior to the expiration of the '289 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 962 of the First Amended Consolidated Complaint, and therefore denies them.

963. On information and belief, Orbicular had knowledge of the '289 patent when it submitted ANDA No. 217868. Orbicular's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 963 of the First Amended Consolidated Complaint, and therefore denies them.

964. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '289 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 964 of the First Amended Consolidated Complaint, and therefore denies them.

965. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 965 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LIX**
**INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY ORBICULAR**

966. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

967. Orbicular's submission of ANDA No. 217868 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Orbicular ANDA Product in/into the United States prior to the expiration of the '531 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 967 of the First Amended Consolidated Complaint, and therefore denies them.

968. Unless enjoined, upon FDA approval of Orbicular's ANDA No. 217868, Orbicular will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 968 of the First Amended Consolidated Complaint, and therefore denies them.

969. On information and belief, upon FDA approval of Orbicular's ANDA No. 217868, Orbicular intends to manufacture, market, sell, and offer to sell Orbicular's ANDA Product with an FDA-approved package insert that will direct healthcare providers and patients in the use of Orbicular's ANDA Product.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 969 of the First Amended Consolidated Complaint, and therefore denies them.

970. On information and belief, Orbicular will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Orbicular knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '531 patent by marketing Orbicular's ANDA Product with the FDA-approved package insert.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 970 of the First Amended Consolidated Complaint, and therefore denies them.

971. The '531 patent has one independent claim, claim 1, which states:

> 1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:
>
> (a) selecting a patient having chronic obstructive pulmonary disease for treatment based on the patient having a peak inspiratory flow rate less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50 percent; and
>
> (b) administering a pharmaceutical composition comprising about 175 μg of revefenacin, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

**ANSWER:** Admitted.

972. A healthcare provider will directly infringe one or more of the claims of the '531 patent. Specifically, a healthcare provider administering Orbicular's ANDA Product in accordance with Orbicular's package insert will perform all of the steps of one or more claims of the '531 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 972 of the First Amended Consolidated Complaint, and therefore denies them.

973. FDA regulations require that approved drug products include prescribing information reciting the FDA-approved indication(s) for the drug and related instructions for healthcare providers to safely and effectively administer the drug. *See* 21 C.F.R. § 201.56(a)(1)¬(3), (d)(1); 21 C.F.R. § 201.57(a)-(c).

**ANSWER:** Paragraph 973 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 973.

974. Consistent with FDA regulations, the package insert for YUPELRI® includes prescribing information that recites the FDA-approved indication for YUPELRI® and provides instructions for healthcare providers and patients to safely and effectively administer YUPELRI®.

**ANSWER:** Paragraph 974 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 974.

975. The package insert for Orbicular's ANDA Product will be substantially similar to the package insert for YUPELRI® in all material respects.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 975 of the First Amended Consolidated Complaint, and therefore denies them.

976. Providers of revefenacin review and follow the package inserts for the revefenacin products they use to treat their patients.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 976 of the First Amended Consolidated Complaint, and therefore denies them.

977. On information and belief, Orbicular is seeking approval to market its ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 977 of the First Amended Consolidated Complaint, and therefore denies them.

978. The YUPELRI® package insert instructs that YUPELRI® is "indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." (Ex. F at § 1).

**ANSWER:** Cipla admits that the YUPELRI® label recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." The remainder of Paragraph 978 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the remaining allegations of Paragraph 978.

979. The "Dosage and Administration" section of the YUPELRI® package instructs that the "recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." (Ex. F at § 2).

**ANSWER:** Cipla admits the YUPELRI ® label recites that "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 979 of the First Amended Consolidated Complaint, and therefore denies them.

980. The "Dosage Form and Strengths" section of the YUPELRI® package insert states that YUPELRI® is an "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." (Ex. F at § 3).

**ANSWER:** Cipla admits that the YUPELRI® label recites "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations containing in Paragraph 980 of the First Amended Consolidated Complaint, and therefore denies them.

981. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 981 of the First Amended Consolidated Complaint, and therefore denies them.

982. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 982 of the First Amended Consolidated Complaint, and therefore denies them.

983. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV1 of 55%. (*Id.*)

**ANSWER:** Cipla admits that the YUPELRI® label recites "[a]t screening, the mean post-bronchodilator percent predicted FEV1 was 55% (range: 10% to 90%), and the post-broncodilator FEV1/FVC ratio was 0.54 (range: 0.3 to 0.7)." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 983 of the First Amended Consolidated Complaint, and therefore denies them.

984. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV1 of equal to or greater than 30% and less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 984 of the First Amended Consolidated Complaint, and therefore denies them.

985. A healthcare provider, or a patient at the direction of a healthcare provider, will administer Orbicular's ANDA Product to the patient once daily using a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 985 of the First Amended Consolidated Complaint, and therefore denies them.

986. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 986 of the First Amended Consolidated Complaint, and therefore denies them.

987. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient's ability to use an inhaler.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 987 of the First Amended Consolidated Complaint, and therefore denies them.

988. It is known that successful use of dry powder inhalers such as the HandiHaler® requires a PIFR of 60 L/min.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 988 of the First Amended Consolidated Complaint, and therefore denies them.

989. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. *See, e.g.*, Mahler 2017; Mahler 2014.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 989 of the First Amended Consolidated Complaint, and therefore denies them.

990. On information and belief, Orbicular specifically intends that its ANDA product, if marketed, would be administered to some patients with moderate to severe COPD having a PIFR of less than about 60 L/min and FEV1 of less than 50%, using a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 990 of the First Amended Consolidated Complaint, and therefore denies them.

991. On information and belief, Orbicular knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 991 of the First Amended Consolidated Complaint, and therefore denies them.

992. On information and belief, Orbicular knows, and specifically intends, that some healthcare providers will select patients for treatment with its proposed ANDA product, if marketed, based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 992 of the First Amended Consolidated Complaint, and therefore denies them.

993. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '531 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 993 of the First Amended Consolidated Complaint, and therefore denies them.

994. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 994 of the First Amended Consolidated Complaint, and therefore denies them.

## COUNT LX
## INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY ORBICULAR

995. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

996. Orbicular's submission of ANDA No. 217868 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Orbicular ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 996 of the First Amended Consolidated Complaint, and therefore denies them.

997. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 997 of the First Amended Consolidated Complaint, and therefore denies them.

998. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 998 of the First Amended Consolidated Complaint, and therefore denies them.

999. On information and belief, Orbicular intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, *i.e.*, prior to the expiration of the '948 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 999 of the First Amended Consolidated Complaint, and therefore denies them.

1000. On information and belief, Orbicular had knowledge of the '948 patent when it submitted the Orbicular '948 Patent Paragraph IV Certification as part of ANDA No. 217868. Orbicular's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1000 of the First Amended Consolidated Complaint, and therefore denies them.

1001. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '948 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1001 of the First Amended Consolidated Complaint, and therefore denies them.

1002. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1002 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LXI**
**INFRINGEMENT OF U.S. PATENT NO. 8,017,783 BY ORBICULAR**

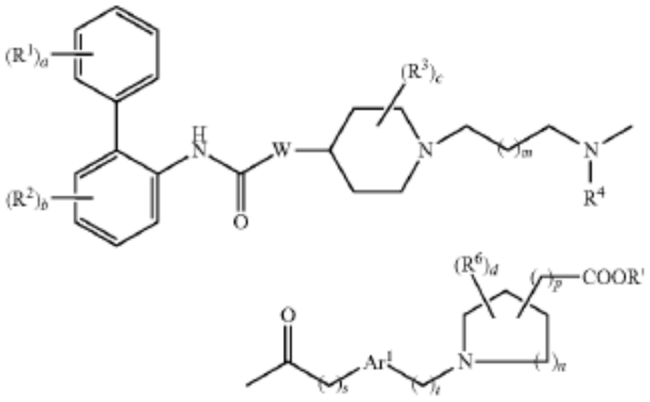
1003. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1004. Claim 1 of the '783 patent recites:

1. A compound of formula XVIII:

XVIII



wherein:

a is 0 or an integer of from 1 to 5;

each $R^1$ is independently selected from (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (3-6C)cycloalkyl, cyano, halo, —$OR^{1a}$, $C(O)OR^{1b}$, —$SR^{1c}$, —$S(O)R^{1d}$, —$S(O)_2R^{1e}$, —$NR^{1f}R^{1g}$, —$NR^{1h}S(O)_2R^{1i}$, and —$NR^{1j}C(O)R^{1k}$; where each of $R^{1a}$, $R^{1b}$, $R^{1c}$, $R^{1d}$, $R^{1e}$, $R^{1f}$, $R^{1g}$, $R^{1h}$, $R^{1i}$, $R^{1j}$, and $R^{1k}$ is independently hydrogen, (1-4C)alkyl or phenyl(1-4C)alkyl;

b is 0 or an integer of from 1 to 4;

each $R^2$ is independently selected from (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (3-6C)cycloalkyl, cyano, halo, —$OR^{2a}$, —$C(O)OR^{2b}$, —$SR^{2c}$, —$S(O)R^{2d}$, —$S(O)_2R^{2e}$, —$NR^{2f}R^{2g}$, —$NR^{2h}S(O)_2R^{2i}$, and —$NR^{2j}C(O)R^{2k}$; where each of $R^{2a}$, $R^{2b}$, $R^{2c}$, $R^{2d}$, $R^{2e}$, $R^{2f}$, $R^{2g}$, $R^{2h}$, $R^{2i}$, $R^{2j}$, and $R^{2k}$ is independently hydrogen, (1-4C)alkyl or phenyl(1-4C)alkyl;

W represents O or $NW^a$, where $W^a$ is hydrogen or (1-4C)alkyl;

c is 0 or an integer from 1 to 5;

each $R^3$ independently represents (1-4C)alkyl or two $R^3$ groups are joined to form (1-3C)alkylene, (2-3C)alkenylene or oxiran-2,3-diyl;

m is 0 or 1;

$R^4$ is selected from hydrogen, (1-4C)alkyl, and (3-4C)cycloalkyl;

s is 0, 1 or 2;

$Ar^1$ represents a phenylene group or a (3-5C)heteroarylene group containing 1 or 2 heteroatoms independently

selected from oxygen, nitrogen, and sulfur; wherein the phenylene or heteroarylene group is substituted with $(R^5)_q$ where q is 0 or an integer from 1 to 4 and each $R^5$ is independently selected from halo, hydroxy, (1-4C) alkyl, and (1-4C)alkoxy;

t is 0, 1 or 2;

n is 0 or an integer from 1 to 3;

d is 0 or an integer from 1 to 4;

each $R^6$ independently represents fluoro or (1-4C)alkyl;

p is 0 or 1; and

R' is selected from hydrogen, $—CH_3$, and $—CH_2CH_3$;

wherein each alkyl and alkoxy group in $R^1$, $R^{1a\text{-}1k}$, $R^2$, $R^{2a\text{-}2k}$, $R^3$, $R^5$, and $R^6$ is optionally substituted with 1 to 5 fluoro substituents;

or a pharmaceutically acceptable salt or stereoisomer thereof.

**ANSWER:** Admitted.

1005. According to the YUPELRI® package insert, in Section 12.3, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 1005 of the First Amended Consolidated Complaint, and therefore denies them.

1006 According to the YUPELRI® package insert, in Section 12.3, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly[.]" Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 1006 of the First Amended Consolidated Complaint, and therefore denies them.

1007. On information and belief, when a patient uses the Orbicular ANDA Product, the revefenacin contained in the Orbicular ANDA Product will undergo hydrolysis of the primary amide to form a carboxcylic acid.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1007 of the First Amended Consolidated Complaint, and therefore denies them.

1008. On information and belief, the compound resulting from that reaction is a compound within the scope of Claim 1 of the '783 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1008 of the First Amended Consolidated Complaint, and therefore denies them.

1009. The commercial use of the product that is the subject of Orbicular's ANDA No. 217868 will constitute an act of infringement of the '783 patent under 35 U.S.C. § 271(b) and (c) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1009 of the First Amended Consolidated Complaint, and therefore denies them.

1010. On information and belief, Orbicular intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, i.e., prior to the expiration of the '783 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1010 of the First Amended Consolidated Complaint, and therefore denies them.

1011. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '783 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1011 of the First Amended Consolidated Complaint, and therefore denies them.

1012. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1012 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LXII**
**INFRINGEMENT OF U.S. PATENT NO. 9,249,099 BY ORBICULAR**

1013. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1014. Claim 1 of the ’099 patent recites:

> 1. A crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1 ylmethyl)benzoyl]methylamino}ethyl)piperidin-4-ylester, characterized by a powder x-ray diffraction pattern having:
>
> (a) two or more diffraction peaks at 2θ values selected from 4.7±0.2, 9.6±0.2, 12.7±0.2, 13.7±0.2, 16.7±0.2, 17.4±0.2, 18.5±0.2, 19.4±0.2, 20.8±0.2, 21.4±0.2, 24.2±0.2, and 25.6±0.2; or
>
> (b) two or more diffraction peaks at 2θ values selected from 4.6±0.2, 9.3±0.2, 12.9±0.2, 13.6±0.2, 14.0±0.2, 14.6±0.2, 16.5±0.2, 18.6±0.2, 19.1±0.2, 20.9±0.2, 22.1±0.2, 22.7±0.2, and 25.7±0.2.

**ANSWER:** Admitted.

1015. On information and belief, Orbicular uses some amount of a compound recited in claim 1 of the ’099 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1015 of the First Amended Consolidated Complaint, and therefore denies them.

1016. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Orbicular's ANDA No. 217868 will constitute acts of infringement of the '099 patent under 35 U.S.C. §§ 271(a) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1016 of the First Amended Consolidated Complaint, and therefore denies them.

1017. On information and belief, Orbicular intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, i.e., prior to the expiration of the '099 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1017 of the First Amended Consolidated Complaint, and therefore denies them.

1018. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '099 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1018 of the First Amended Consolidated Complaint, and therefore denies them.

1019. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1019 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LXIII**

**INFRINGEMENT OF U.S. PATENT NO. 10,100,013 BY ORBICULAR**

1020. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1021. Claim 1 of the '013 patent recites:

> 1. A method for preparing a pharmaceutical composition for use in a nebulizer inhaler, the method comprising dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}
>
> ethyl)piperidin-4-yl ester in an aqueous pharmaceutical carrier to form an aqueous solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Admitted.

1022. On information and belief, the manufacture of Orbicular's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1022 of the First Amended Consolidated Complaint, and therefore denies them.

1023. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Orbicular's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '013 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1023 of the First Amended Consolidated Complaint, and therefore denies them.

1024. Plaintiffs have requested relevant discovery from Orbicular to confirm these characteristics of Orbicular's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Orbicular's ANDA Product—but have not

received said discovery as of the date of this First Amended Complaint. Orbicular has an affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1024 of the First Amended Consolidated Complaint, and therefore denies them.

1025. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Orbicular's ANDA No. 217868 will constitute acts of infringement of the '013 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1025 of the First Amended Consolidated Complaint, and therefore denies them.

1026. On information and belief, Orbicular intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, i.e., prior to the expiration of the '013 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1026 of the First Amended Consolidated Complaint, and therefore denies them.

1027. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '013 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1027 of the First Amended Consolidated Complaint, and therefore denies them.

1028. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1028 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LXIV**
**INFRINGEMENT OF U.S. PATENT NO. 11,649,209 BY ORBICULAR**

1029. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1030. Claim 1 of the '209 patent recites:

> 1. A process for preparing a pharmaceutical composition, the process comprising:
>
> dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-l-ylmethyl)benzoyl)]methylamino}-ethyl)piperidin-4-yl ester in a solvent to form a solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1,
>
> 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Admitted.

1031. On information and belief, the manufacture of Orbicular's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1031 of the First Amended Consolidated Complaint, and therefore denies them.

1032. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Orbicular's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '209 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1032 of the First Amended Consolidated Complaint, and therefore denies them.

1033. Plaintiffs have requested relevant discovery from Orbicular to confirm these characteristics of Orbicular's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Orbicular's ANDA Product—but have not received said discovery as of the date of this First Amended Complaint. Orbicular has an affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1033 of the First Amended Consolidated Complaint, and therefore denies them.

1034. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Orbicular's ANDA No. 217868 will constitute acts of infringement of the '209 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1034 of the First Amended Consolidated Complaint, and therefore denies them.

1035. On information and belief, Orbicular intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, i.e., prior to the expiration of the '209 patent.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1035 of the First Amended Consolidated Complaint, and therefore denies them.

1036. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '209 patent is not enjoined.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1036 of the First Amended Consolidated Complaint, and therefore denies them.

1037. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1037 of the First Amended Consolidated Complaint, and therefore denies them.

**COUNT LXV**
**INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY CIPLA**

1038. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1039. Cipla's submission of ANDA No. 217958 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Cipla ANDA Product in/into the United States prior to the expiration of the '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

1040. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

1041. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

**ANSWER:** Denied.

1042. On information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '451 patent.

**ANSWER:** Cipla denies the allegations of Paragraph 1042 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

1043. On information and belief, Cipla had knowledge of the '451 patent when it submitted ANDA No. 217958. Cipla's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla admits that it had knowledge of the '451 patent when it submitted ANDA No. 217958. Cipla denies the remaining allegations in Paragraph 1043 of the First Amended Consolidated Complaint.

1044. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '451 patent is not enjoined.

**ANSWER:** Denied.

1045. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

**COUNT LXVI**
**INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY CIPLA**

1046. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1047. Cipla's submission of ANDA No. 217958 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Cipla ANDA Product in/into the United States prior to the expiration of the '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

1048. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

1049. On information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '028 patent.

**ANSWER:** Cipla denies the allegations of Paragraph 1049 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

1050. On information and belief, Cipla had knowledge of the '028 patent when it submitted ANDA No. 217958. Cipla's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla admits that it had knowledge of the '028 patent when it submitted ANDA No. 217958. Cipla denies the remaining allegations in Paragraph 1050 of the First Amended Consolidated Complaint.

1051. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '028 patent is not enjoined.

**ANSWER:** Denied.

1052. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

**COUNT LXVII**
**INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY CIPLA**

1053. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1054. Cipla's submission of ANDA No. 217958 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer

for sale, and/or sale of the Cipla ANDA Product in/into the United States prior to the expiration of the '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

1055. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

1056. On information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

**ANSWER:** Cipla denies the allegations of Paragraph 1056 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

1057. On information and belief, Cipla had knowledge of the '081 patent when it submitted ANDA No. 217958. Cipla's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla admits that it had knowledge of the '081 patent when it submitted ANDA No. 217958. Cipla denies the remaining allegations in Paragraph 1057 of the First Amended Consolidated Complaint.

1058. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '081 patent is not enjoined.

**ANSWER:** Denied.

1059. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

**COUNT LXVIII**
**INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY CIPLA**

1060. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1061. Cipla's submission of ANDA No. 217958 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Cipla ANDA Product in/into the United States prior to the expiration of the '289 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

1062. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

**ANSWER:** Denied.

1063. On information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '289 patent.

**ANSWER:** Cipla denies the allegations of Paragraph 1063 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

1064. On information and belief, Cipla had knowledge of the '289 patent when it submitted ANDA No. 217958. Cipla's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla admits that it had knowledge of the '289 patent when it submitted ANDA No. 217958. Cipla denies the remaining allegations in Paragraph 1064 of the First Amended Consolidated Complaint.

1065. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '289 patent is not enjoined.

**ANSWER:** Denied.

1066. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

**COUNT LXIX**
**INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY CIPLA**

1067. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1068. Cipla's submission of ANDA No. 217958 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Cipla ANDA Product in/into the United States prior to the expiration of the '531 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

1069. Unless enjoined, upon FDA approval of Cipla's ANDA No. 217958, Cipla will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

**ANSWER:** Denied.

1070. On information and belief, upon FDA approval of Cipla's ANDA No. 217958, Cipla intends to manufacture, market, sell, and offer to sell Cipla's ANDA Product with an FDA-approved package insert that will direct healthcare providers and patients in the use of Cipla's ANDA Product.

**ANSWER:** Cipla denies the allegations of Paragraph 1070 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

1071. On information and belief, Cipla will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Cipla knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '531 patent by marketing Cipla's ANDA Product with the FDA-approved package insert.

**ANSWER:** Denied.

1072. The '531 patent has one independent claim, claim 1, which states:

> 1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:
>
> (a) selecting a patient having chronic obstructive pulmonary disease

for treatment based on the patient having a peak inspiratory flow rate less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50 percent; and

(b) administering a pharmaceutical composition comprising about 175 µg of revefenacin, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

**ANSWER:** Admitted.

1073. A healthcare provider will directly infringe one of more of the claims of the '531 patent. Specifically, a healthcare provider administering Cipla's ANDA Product in accordance with Cipla's package insert will perform all of the steps of one or more claims of the '531 patent.

**ANSWER:** Denied.

1074. FDA regulations require that approved drug products include prescribing information reciting the FDA-approved indication(s) for the drug and related instructions for healthcare providers to safely and effectively administer the drug. *See* 21 C.F.R. § 201.56(a)(1)¬(3), (d)(1); 21 C.F.R. § 201.57(a)-(c).

**ANSWER:** Paragraph 1074 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 1074.

1075. Consistent with FDA regulations, the package insert for YUPELRI® includes prescribing information that recites the FDA-approved indication for YUPELRI® and provides instructions for healthcare providers and patients to safely and effectively administer YUPELRI®.

**ANSWER:** Paragraph 1075 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 1075.

1076. The package insert for Cipla's ANDA Product will be substantially similar to the package insert for YUPELRI® in all material respects.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1076 of the First Amended Consolidated Complaint, and therefore denies them.

1077. Providers of revefenacin review and follow the package inserts for the revefenacin products they use to treat their patients.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1077 of the First Amended Consolidated Complaint, and therefore denies them.

1078. On information and belief, Cipla is seeking approval to market its ANDA Product for the same approved indication as YUPELRI®.

**ANSWER:** Admitted.

1079. The YUPELRI® package insert instructs that YUPELRI® is "indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." (Ex. F at § 1).

**ANSWER:** Cipla admits that the YUPELRI® label recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." The remainder of Paragraph 1079 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the remaining allegations of Paragraph 1079.

1080. The "Dosage and Administration" section of the YUPELRI® package instructs that the "recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." (Ex. F at § 2).

**ANSWER:** Cipla admits that the YUPELRI® label recites "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 1080 of the First Amended Consolidated Complaint, and therefore denies them.

1081. The "Dosage Form and Strengths" section of the YUPELRI® package insert states that YUPELRI® is an "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." (Ex. F at § 3).

**ANSWER:** Cipla admits that the YUPELRI® label recites "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous olution in unit dose vials." Cipla

is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 1081 of the First Amended Consolidated Complaint, and therefore denies them.

1082. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1082 of the First Amended Consolidated Complaint, and therefore denies them.

1083. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1083 of the First Amended Consolidated Complaint, and therefore denies them.

1084. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV1 of 55%. (*Id.*)

**ANSWER:** Cipla admits that the YUPELRI® label recites "[a]t screening, the mean post-bronchodilator percent predicted FEV1 was 55% (range: 10% to 90%), and the post-bronchodilator FEV1/FVC ratio was 0.54 (range: 0.3 to 0.7)." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 1084 of the First Amended Consolidated Complaint, and therefore denies them.

1085. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV1 of equal to or greater than 30% and less than 50%.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1085 of the First Amended Consolidated Complaint, and therefore denies them.

1086. A healthcare provider, or a patient at the direction of a healthcare provider, will administer Cipla's ANDA Product to the patient once daily using a nebulizer.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1086 of the First Amended Consolidated Complaint, and therefore denies them.

1087. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

**ANSWER:** Cipla admit that the YUPELRI® label recites "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 1087 of the First Amended Consolidated Complaint, and therefore denies them.

1088. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient's ability to use an inhaler.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1088 of the First Amended Consolidated Complaint, and therefore denies them.

1089. It is known that successful use of dry powder inhalers such as the HandiHaler® requires a PIFR of 60 L/min.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1089 of the First Amended Consolidated Complaint, and therefore denies them.

1090. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. *See, e.g.*, Mahler 2017; Mahler 2014.

**ANSWER:** Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 1090 of the First Amended Consolidated Complaint, and therefore denies them.

1091. On information and belief, Cipla specifically intends that its ANDA product, if marketed, would be administered to some patients with moderate to severe COPD having a PIFR of less than about 60 L/min and FEV1 of less than 50%, using a nebulizer.

**ANSWER:** Denied.

1092. On information and belief, Cipla knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Denied.

1093. On information and belief, Cipla knows, and specifically intends, that some healthcare providers will select patients for treatment with its proposed ANDA product, if marketed, based on the patient having a PIFR of less than about 60 L/min and FEV1 of less than 50%.

**ANSWER:** Denied.

1094. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '531 patent is not enjoined.

**ANSWER:** Denied.

1095. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

**COUNT LXX**
**INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY CIPLA**

1096. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1097. Cipla's submission of ANDA No. 217958 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Cipla ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

1098. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

1099. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

**ANSWER:** Denied.

1100. On information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '948 patent.

**ANSWER:** Cipla denies the allegations of Paragraph 1100 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

1101. On information and belief, Cipla has knowledge of the '948 patent. Cipla's infringement has been, and continues to be, deliberate.

**ANSWER:** Cipla admits that it had knowledge of the '948 patent when it submitted ANDA No. 217958. Cipla denies the remaining allegations in Paragraph 1101 of the First Amended Consolidated Complaint.

1102. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '948 patent is not enjoined.

**ANSWER:** Denied.

1103. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

**COUNT LXXI**
**INFRINGEMENT OF U.S. PATENT NO. 8,017,783 BY CIPLA**

1104. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1105. Claim 1 of the '783 patent recites:

> selected from oxygen, nitrogen, and sulfur; wherein the phenylene or heteroarylene group is substituted with $(R^5)_q$ where q is 0 or an integer from 1 to 4 and each $R^5$ is independently selected from halo, hydroxy, (1-4C) alkyl, and (1-4C)alkoxy;
> t is 0, 1 or 2;
> n is 0 or an integer from 1 to 3;
> d is 0 or an integer from 1 to 4;
> each $R^6$ independently represents fluoro or (1-4C)alkyl;
> p is 0 or 1; and
> R' is selected from hydrogen, $—CH_3$, and $—CH_2CH_3$;
> wherein each alkyl and alkoxy group in $R^1$, $R^{1a-1k}$, $R^2$, $R^{2a-2k}$, $R^3$, $R^5$, and $R^6$ is optionally substituted with 1 to 5 fluoro substituents;
> or a pharmaceutically acceptable salt or stereoisomer thereof.
> selected from oxygen, nitrogen, and sulfur; wherein the phenylene or heteroarylene group is substituted with $(R^5)_q$ where q is 0 or an integer from 1 to 4 and each $R^5$ is independently selected from halo, hydroxy, (1-4C) alkyl, and (1-4C)alkoxy;
> t is 0, 1 or 2;
> n is 0 or an integer from 1 to 3;
> d is 0 or an integer from 1 to 4;
> each $R^6$ independently represents fluoro or (1-4C)alkyl;
> p is 0 or 1; and
> R' is selected from hydrogen, $—CH_3$, and $—CH_2CH_3$;
> wherein each alkyl and alkoxy group in $R^1$, $R^{1a-1k}$, $R^2$, $R^{2a-2k}$, $R^3$, $R^5$, and $R^6$ is optionally substituted with 1 to 5 fluoro substituents;
> or a pharmaceutically acceptable salt or stereoisomer thereof.

**ANSWER:** Admitted.

1106. According to the YUPELRI® package insert, in Section 12.3, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "*[i]n vitro* and *in vivo* data showed that revefenacin is primarily metabolized via hydrolysis of the primary amide to a carboxylic acid forming its major active metabolite." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 1106 of the First Amended Consolidated Complaint, and therefore denies them.

1107. According to the YUPELRI® package insert, in Section 12.3, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly." (Ex. F at § 12.3).

**ANSWER:** Cipla admits that the YUPELRI® label recites, "[f]ollowing inhaled administration of YUPELRI in COPD patients, conversion to its active metabolite occurred rapidly[.]" Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 1107 of the First Amended Consolidated Complaint, and therefore denies them.

1108. On information and belief, when a patient uses the Cipla ANDA Product, the revefenacin contained in the Cipla ANDA Product will undergo hydrolysis of the primary amide to form a carboxcylic acid.

**ANSWER:** Denied.

1109. On information and belief, the compound resulting from that reaction is a compound within the scope of Claim 1 of the '783 patent.

**ANSWER:** Denied.

1110. The commercial use of the product that is the subject of Cipla's ANDA No. 217958 will constitute an act of infringement of the '783 patent under 35 U.S.C. § 271(b) and (c) unless enjoined by the Court.

**ANSWER:** Denied.

1111. On information and belief, Cipla intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon

the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '783 patent.

**ANSWER:** Cipla denies the allegations of Paragraph 1111 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

1112. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '783 patent is not enjoined

**ANSWER:** Denied.

1113. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

**COUNT LXXII**
**INFRINGEMENT OF U.S. PATENT NO. 9,249,099 BY CIPLA**

1114. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1115. Claim 1 of the '099 patent recites:

> 1. A crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}ethyl)piperidin-4-yl ester, characterized by a powder x-ray diffraction pattern having:
>
> (a) two or more diffraction peaks at 2θ values selected from 4.7±0.2, 9.6±0.2, 12.7±0.2, 13.7±0.2, 16.7±0.2, 17.4±0.2, 18.5±0.2, 19.4±0.2, 20.8±0.2, 21.4±0.2, 24.2±0.2, and 25.6±0.2; or
>
> (b) two or more diffraction peaks at 2θ values selected from 4.6±0.2, 9.3±0.2, 12.9±0.2, 13.6±0.2, 14.0±0.2, 14.6±0.2, 16.5±0.2, 18.6±0.2, 19.1±0.2, 20.9±0.2, 22.1±0.2, 22.7±0.2, and 25.7±0.2.

**ANSWER:** Admitted.

1116. On information and belief, Cipla uses some amount of a compound recited in claim 1 of the '099 patent.

**ANSWER:** Denied.

1117. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Cipla's ANDA No. 217958 will constitute acts of infringement of the '099 patent under 35 U.S.C. §§ 271(a) and/or (g) unless enjoined by the Court.

**ANSWER:** Denied.

1118. On information and belief, Cipla intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '099 patent.

**ANSWER:** Cipla denies the allegations of Paragraph 1118 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

1119. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '099 patent is not enjoined.

**ANSWER:** Denied.

1120. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

## COUNT LXXIII
## INFRINGEMENT OF U.S. PATENT NO. 10,100,013 BY CIPLA

1121. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1122. Claim 1 of the '013 patent recites:

> 1. A method for preparing a pharmaceutical composition for use in a nebulizer inhaler, the method comprising dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}
>
> ethyl)piperidin-4-yl ester in an aqueous pharmaceutical carrier to form an aqueous solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Admitted.

1123. On information and belief, the manufacture of Cipla's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Denied.

1124. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Cipla's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '013 patent.

**ANSWER:** Denied.

1125. Plaintiffs have requested relevant discovery from Cipla to confirm these characteristics of Cipla's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Cipla's ANDA Product—but have not received said discovery as of the date of this First Amended Complaint. Cipla has an affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Denied.

1126. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Cipla's ANDA No. 217958 will constitute acts of infringement of the '013 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Denied.

1127. On information and belief, Cipla intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '013 patent.

**ANSWER:** Cipla denies the allegations of Paragraph 1127 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

1128. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '013 patent is not enjoined.

**ANSWER:** Denied.

1129. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

**COUNT LXXIV**
**INFRINGEMENT OF U.S. PATENT NO. 11,649,209 BY CIPLA**

1130. Plaintiffs incorporate by reference the prior paragraphs of this First Amended Complaint as if fully set forth herein.

**ANSWER:** Cipla repeats and realleges its responses to the prior paragraphs of the First Amended Consolidated Complaint as if fully set forth herein.

1131. Claim 1 of the '209 patent recites:

> 1. A process for preparing a pharmaceutical composition, the process comprising:
>
> dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-l-ylmethyl)benzoyl)]methylamino}-ethyl)piperidin-4-yl ester in a solvent to form a solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

**ANSWER:** Admitted.

1132. On information and belief, the manufacture of Cipla's ANDA Product involves dissolving a crystalline freebase of revefenacin in an aqueous pharmaceutical carrier to form an aqueous solution.

**ANSWER:** Denied.

1133. On information and belief, the crystalline freebase of revefenacin used in the manufacture of Cipla's ANDA Product has powder x-ray diffraction peaks at 2θ values corresponding to those recited in claim 1 of the '209 patent.

**ANSWER:** Denied.

1134. Plaintiffs have requested relevant discovery from Cipla to confirm these characteristics of Cipla's ANDA Product—including but not limited to samples of the active pharmaceutical ingredient used in the manufacture of Cipla's ANDA Product—but have not received said discovery as of the date of this First Amended Complaint. Cipla has an affirmative obligation to provide any non-infringement defense(s) and, accordingly, has not met its obligation.

**ANSWER:** Denied.

1135. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Cipla's ANDA No. 217958 will constitute acts of infringement of the '209 patent under 35 U.S.C. §§ 271(b) and/or (g) unless enjoined by the Court.

**ANSWER:** Denied.

1136. On information and belief, Cipla intends to engage in and/or induce another to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '209 patent.

**ANSWER:** Cipla denies the allegations of Paragraph 1136 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

1137. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '209 patent is not enjoined.

**ANSWER:** Denied.

1138. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

## PRAYER FOR RELIEF

Cipla denies that Plaintiffs are entitled to the relief sought in paragraphs (a) through (yyy) on pages 202 through 213 of the First Amended Consolidated Complaint. Should Plaintiffs receive any of their requested relief, no such relief should prevent Cipla from obtaining a Pre-Launch Activities Importation Request from the FDA, or acting under it, in connection with Cipla's ANDA Product.

## AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 1138 of the First Amended Consolidated Complaint, Cipla alleges the following Separate Defenses to the Complaint. Cipla expressly reserves the right to allege additional defenses as they become known through the course of discovery or other factual investigation. Cipla does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

**First Defense**
**(Invalidity of the '451 Patent)**

Each claim of the '451 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Second Defense**
**(Noninfringement of the '451 Patent)**

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '451 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '451 patent, either literally or under the doctrine of equivalents.

**Third Defense**
**(Invalidity of the '028 Patent)**

Each claim of the '028 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Fourth Defense**
**(Noninfringement of the '028 Patent)**

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '028 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '028 patent, either literally or under the doctrine of equivalents.

**Fifth Defense**
**(Invalidity of the '081 Patent)**

Each claim of the '081 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Sixth Defense**
**(Noninfringement of the '081 Patent)**

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '081 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '081 patent, either literally or under the doctrine of equivalents.

**Seventh Defense**
**(Invalidity of the '289 Patent)**

Each claim of the '289 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Eighth Defense**
**(Noninfringement of the '289 Patent)**

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '289 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '289 patent, either literally or under the doctrine of equivalents.

**Ninth Defense**
**(Invalidity of the '531 Patent)**

Each claim of the '531 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Tenth Defense**
**(Noninfringement of the '531 Patent)**

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '531 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '531 patent, either literally or under the doctrine of equivalents.

**Eleventh Defense**
**(Invalidity of the '948 Patent)**

Each claim of the '948 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Twelvth Defense**
**(Noninfringement of the '948 Patent)**

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '948 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '948 patent, either literally or under the doctrine of equivalents.

**Thirteenth Defense**
**(Invalidity of the '783 Patent)**

Each claim of the ’783 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Fourteenth Defense**
**(Noninfringement of the ’783 Patent)**

Cipla has not, does not, and will not infringe any valid and enforceable claim of the ’783 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the ’783 patent, either literally or under the doctrine of equivalents.

**Fifteenth Defense**
**(Invalidity of the ’099 Patent)**

Each claim of the ’099 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Sixteenth Defense**
**(Noninfringement of the ’099 Patent)**

Cipla has not, does not, and will not infringe any valid and enforceable claim of the ’099 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the ’531 patent, either literally or under the doctrine of equivalents.

**Seventeenth Defense**
**(Invalidity of the ’013 Patent)**

Each claim of the ’013 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Eighteenth Defense**
**(Noninfringement of the ’013 Patent)**

Cipla has not, does not, and will not infringe any valid and enforceable claim of the ’013 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the ’531 patent, either literally or under the doctrine of equivalents.

**Nineteenth Defense**
**(Invalidity of the ’209 Patent)**

Each claim of the ’209 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Twentieth Defense**
**(Noninfringement of the ’209 Patent)**

Cipla has not, does not, and will not infringe any valid and enforceable claim of the ’209 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the ’209 patent, either literally or under the doctrine of equivalents.

**Twenty-First Defense**
**(Waiver)**

Plaintiffs have waived any defect in the manner in which Cipla served Cipla’s Notice Letters and/or are estopped from contesting any alleged defect in service of Cipla’s Notice Letters.

**Twenty-Second Defense**

**(Estoppel)**

Plaintiffs are estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

**Twenty-Third Defense**
**(Failure to State a Claim)**

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

**Twenty-Fourth Defense**
**(No Exceptional Case)**

Cipla's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

**Twenty-Fifth Defense**
**(No Willful Infringement)**

Cipla has not willfully infringed any claim of the Asserted Patents.

**COUNTERCLAIMS**

Without admitting the allegations of Plaintiffs Theravance Biopharma R&D IP, LLC, Theravance Biopharma Ireland Limited, Theravance Biopharma US, Inc., Mylan Ireland Limited, and Mylan Specialty L.P. (collectively, "Plaintiffs" or "Counterclaim Defendants") other than those expressly admitted herein, Defendants Cipla Limited and Cipla USA, Inc. (collectively, "Cipla" or "Defendants" or "Counterclaim Plaintiffs") bring the following Counterclaims against Plaintiffs/Counterclaim Defendants for declaratory judgment that United States Patent Nos. 8,541,451 (the "'451 patent"), 9,765,028 (the "'028 patent"), 10,550,081 (the "'081 patent"), 11,008,289 (the "'289 patent"), and 11,484,531 (the "'531 patent"), 11,691,948 (the "'948 patent"), 8,017,783 (the "'783 patent"), 9,249,099 (the "'099 patent"), the 10,100,013 (the "'013 patent"), and 11,649,209 (the "'209 patent") (hereinafter collectively referred to as the "Patents-in-Suit")

are invalid and/or not infringed by Cipla and the product as described in Cipla's Abbreviated New Drug Application No. 217958 ("Cipla's ANDA Product").

**The Parties**

1. Counterclaim Plaintiff Cipla Limited is an entity organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400 013, India.

2. Counterclaim Plaintiff Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059.

3. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Theravance Biopharma R&D IP, LLC is a Delaware limited liability company having a principal place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080.

4. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Theravance Biopharma Ireland Limited is an Irish company having a registered office at Ten Earlsfort Terrace, Dublin 2, D02 T380, Ireland.

5. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Theravance Biopharma US, Inc. is a Delaware corporation having a principal place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080.

6. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Mylan Ireland Limited is a company having a principal place of business at Newenham Court, Northern Cross, Malahide Road, Dublin 17, Ireland; and a registered office at Unit 35/36, Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland.

7. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Mylan Specialty L.P. is a company having a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia, 26505.

8. Upon information and belief, Counterclaim Defendant Mylan Ireland Limited is also the holder of approved New Drug Application No. 210598 for YUPELRI® (revefenacin).

9. Upon information and belief, Counterclaim Defendants Mylan Specialty L.P. and Theravance Biopharma US, Inc. currently promote and market YUPELRI® in the United States.

**Jurisdiction and Venue**

10. This court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367, based on an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*

11. This Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants have availed themselves of the rights and privileges and subjected themselves to the jurisdiction of this forum by suing Cipla in this judicial district.

12. Venue is proper in this district for the purposes of these Counterclaims because Counterclaim Defendants filed the present action in this district.

13. On or about February 16, 2023 and August 21, 2023, Counterclaim Defendants filed civil actions in this judicial district against Cipla alleging infringement of certain of the Patents-in-Suit (’451 patent, ’028 patent, ’081 patent, ’289 patent, ’531 patent, and ’948 patent). Plaitiffs have herein since added infringement allegations with respect to the ’783 patent, the ’099 patent, the ’013 patent, and the ’209 patent with respect to Cipla and to these now-consolidated actions. There is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and

reality to warrant the issuance of a declaratory judgment regarding Cipla and Cipla's ANDA Product's non-infringement of the Patents-in-Suit.

**The Patents-in-Suit**

14. Based on the allegations in the Complaint, the '451 patent, entitled "Crystalline Freebase Forms of a Biphenyl Compound," was issued on September 24, 2013. The U.S. Patent and Trademark Office lists Theravance Biopharma R&D IP, LLC as the assignee of the '451 patent.

15. Based on the allegations in the Complaint, the '028 patent, entitled "Crystalline Freebase Forms of a Biphenyl Compound," was issued on September 19, 2017. The face of the '028 patent lists Theravance Biopharma R&D IP, LLC as the assignee.

16. Based on the allegations in the Complaint, the '081 patent, entitled "Crystalline Freebase Forms of a Biphenyl Compound," was issued on February 4, 2020. The face of the '081 patent lists Theravance Biopharma R&D IP, LLC as the assignee.

17. Based on the allegations in the Complaint, the '289 patent, entitled "Crystalline Freebase Forms of a Biphenyl Compound," was issued on May 18, 2021. The face of the '289 patent lists Theravance Biopharma R&D IP, LLC as the assignee.

18. Based on the allegations in the Complaint, the '531 patent, entitled "Methods for Treating Chronic Obstructive Pulmonary Disease," was issued on November 1, 2022. The face of the '531 patent lists Theravance Biopharma R&D IP, LLC as the assignee.

19. Based on the allegations in the Complaint, the '948 patent, entitled "Crystalline Freebase Forms of a Biphenyl Compound," was issued on July 4, 2023. The U.S. Patent and Trademark Office lists Theravance Biopharma R&D IP, LLC as the assignee of the '948 patent.

20. Based on the allegations in the Complaint, the '783 patent, entitled "Biphenyl Compounds Useful as Muscarinic Receptor Antagonists," was issued on September 13, 2011. The

U.S. Patent and Trademark Office lists Theravance Biopharma R&D IP, LLC as the assignee of the ’783 patent.

21. Based on the allegations in the Complaint, the ’099 patent, entitled “Crystalline Forms of a Biphenyl Compound,” was on February 2, 2016. The U.S. Patent and Trademark Office lists Theravance Biopharma R&D IP, LLC as the assignee of the ’099 patent.

22. Based on the allegations in the Complaint, the ’013 patent, entitled “Crystalline Freebase Forms of a Biphenyl Compound,” was issued on October 16, 2018. The U.S. Patent and Trademark Office lists Theravance Biopharma R&D IP, LLC as the assignee of the ’013 patent.

23. Based on the allegations in the Complaint, the ’209 patent, entitled “Crystalline Freebase Forms of a Biphenyl Compound,” was issued on May 16, 2023. The U.S. Patent and Trademark Office does not currently list an assignee for the ’209 patent.

24. The ’451, ’028, ’081, ’289, ’531, and ’948 Patents-in-Suit are listed in the Orange Book in association with YUPELRI®. The ’783, ’099, ’013, and ’209 Patents-in-Suit are not listed in the Orange Book in association with YUPELRI®.

25. On January 17, 2023, Cipla sent Counterclaim Defendants Mylan Ireland Ltd. and Theravance Biopharma R&D IP, LLC notification of Paragraph IV Certification for the Patents-in-Suit with respect to Cipla’s filing of ANDA No. 217958 (“Cipla’s First Notice Letter ”), pursuant to 21 U.S.C. §355(j)(2)(B)(ii), (iv) and 21 C.F.R. § 314.95(c)(1).

26. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), Cipla’s First Notice Letter included, among other things, Cipla’s detailed factual and legal basis for the Paragraph IV Certification regarding the ’451, ’028, ’081, ’289, and ’531 Patents-in-Suit as it pertains to Cipla’s ANDA Product and an Offer of Confidential Access to Cipla’s ANDA Product.

27. On August 24, 2023, Cipla sent Counterclaim Defendants Mylan Ireland Ltd. and Theravance Biopharma R&D IP, LLC notification of Paragraph IV Certification for the '948 Patent-in-Suit with respect to Cipla's filing of ANDA No. 217958 ("Cipla's Second Notice Letter"), pursuant to 21 U.S.C. §355(j)(2)(B)(ii), (iv) and 21 C.F.R. § 314.95(c)(1).

28. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), Cipla's Notice Letter included, among other things, Cipla's detailed factual and legal basis for the Paragraph IV Certification regarding the '948 patent as it pertains to Cipla's ANDA Product and an Offer of Confidential Access to Cipla's ANDA Product.

29. On or about December 4, 2023, Counterclaim Defendants filed the instant First Amended Consolidated Complaint alleging infringement of the additional Patents-in-Suit enumerated in Paragraph 13 above.

**First Counterclaim**
**(Declaratory Judgment of Noninfringement of the '451 Patent)**

30. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 29 of the Counterclaims as if fully set forth herein.

31. Counterclaim Defendants have accused Cipla of infringing the '451 patent.

32. Cipla denies infringement of the '451 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '451 patent.

33. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '451 patent.

34. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '451 patent.

**Second Counterclaim**
**(Declaratory Judgment of Invalidity of the '451 Patent)**

35. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 34 of the Counterclaims as if fully set forth herein.

36. The claims of the '451 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

37. For at least the reasons stated in Cipla's First Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '451 patent are not infringed by Cipla's ANDA Product and/or are invalid.

38. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '451 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

39. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '451 patent.

40. Cipla is entitled to a judicial declaration that all claims of the '451 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double

patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Third Counterclaim**
**(Declaratory Judgment of Noninfringement of the '028 Patent)**

41. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 40 of the Counterclaims as if fully set forth herein.

42. Counterclaim Defendants have accused Cipla of infringing the '028 patent.

43. Cipla denies infringement of the '028 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '028 patent.

44. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '028 patent.

45. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '028 patent.

**Fourth Counterclaim**
**(Declaratory Judgment of Invalidity of the '028 Patent)**

46. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 45 of the Counterclaims as if fully set forth herein.

47. The claims of the '028 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not

limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

48. For at least the reasons stated in Cipla's First Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '028 patent are not infringed by Cipla's ANDA Product and/or are invalid.

49. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '028 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

50. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '028 patent.

51. Cipla is entitled to a judicial declaration that all claims of the '028 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Fifth Counterclaim**
**(Declaratory Judgment of Noninfringement of the '081 Patent)**

52. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 51 of the Counterclaims as if fully set forth herein.

53. Counterclaim Defendants have accused Cipla of infringing the '081 patent.

54. Cipla denies infringement of the '081 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if

marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '081 patent.

55. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '081 patent.

56. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '081 patent.

**Sixth Counterclaim**
**(Declaratory Judgment of Invalidity of the '081 Patent)**

57. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 56 of the Counterclaims as if fully set forth herein.

58. The claims of the '081 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

59. For at least the reasons stated in Cipla's First Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '081 patent are not infringed by Cipla's ANDA Product and/or are invalid.

60. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '081 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

61. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the ’081 patent.

62. Cipla is entitled to a judicial declaration that all claims of the ’081 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Seventh Counterclaim**
**(Declaratory Judgment of Noninfringement of the ’289 Patent)**

63. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 62 of the Counterclaims as if fully set forth herein.

64. Counterclaim Defendants have accused Cipla of infringing the ’289 patent.

65. Cipla denies infringement of the ’289 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’289 patent.

66. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the ’289 patent.

67. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '289 patent.

**Eighth Counterclaim**
**(Declaratory Judgment of Invalidity of the '289 Patent)**

68. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 67 of the Counterclaims as if fully set forth herein.

69. The claims of the '289 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

70. For at least the reasons stated in Cipla's First Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '289 patent are not infringed by Cipla's ANDA Product and/or are invalid.

71. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '289 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

72. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '289 patent.

73. Cipla is entitled to a judicial declaration that all claims of the '289 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double

patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Ninth Counterclaim**
**(Declaratory Judgment of Noninfringement of the '531 Patent)**

74. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 73 of the Counterclaims as if fully set forth herein.

75. Counterclaim Defendants have accused Cipla of infringing the '531 patent.

76. Cipla denies infringement of the '531 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '531 patent.

77. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '531 patent.

78. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '531 patent.

**Tenth Counterclaim**
**(Declaratory Judgment of Invalidity of the '531 Patent)**

79. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 78 of the Counterclaims as if fully set forth herein.

80. The claims of the '531 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not

limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

81. For at least the reasons stated in Cipla's First Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '531 patent are not infringed by Cipla's ANDA Product and/or are invalid.

82. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '531 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

83. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '531 patent.

84. Cipla is entitled to a judicial declaration that all claims of the '531 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Ninth Counterclaim**
**(Declaratory Judgment of Noninfringement of the '948 Patent)**

85. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 84 of the Counterclaims as if fully set forth herein.

86. Counterclaim Defendants have accused Cipla of infringing the '948 patent.

87. Cipla denies infringement of the '948 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if

marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’948 patent.

88. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the ’948 patent.

89. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla’s ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the ’948 patent.

**Tenth Counterclaim**
**(Declaratory Judgment of Invalidity of the ’948 Patent)**

90. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 89 of the Counterclaims as if fully set forth herein.

91. The claims of the ’948 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

92. For at least the reasons stated in Cipla’s Second Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the ’948 patent are not infringed by Cipla’s ANDA Product and/or are invalid.

93. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla’s ANDA Product is infringing the claims of the ’948 patent and will continue to try to interfere with Cipla’s business with respect to Cipla’s ANDA Product.

94. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '948 patent.

95. Cipla is entitled to a judicial declaration that all claims of the '948 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Ninth Counterclaim**
**(Declaratory Judgment of Noninfringement of the '783 Patent)**

96. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 95 of the Counterclaims as if fully set forth herein.

97. Counterclaim Defendants have accused Cipla of infringing the '783 patent.

98. Cipla denies infringement of the '783 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '783 patent.

99. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '783 patent.

100. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '783 patent.

**Tenth Counterclaim**
**(Declaratory Judgment of Invalidity of the '783 Patent)**

101. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 100 of the Counterclaims as if fully set forth herein.

102. The claims of the '783 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

103. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '783 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

104. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '783 patent.

105. Cipla is entitled to a judicial declaration that all claims of the '783 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Ninth Counterclaim**
**(Declaratory Judgment of Noninfringement of the '099 Patent)**

106. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 105 of the Counterclaims as if fully set forth herein.

107. Counterclaim Defendants have accused Cipla of infringing the '099 patent.

108. Cipla denies infringement of the '099 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '099 patent.

109. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '099 patent.

110. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '099 patent.

**Tenth Counterclaim**
**(Declaratory Judgment of Invalidity of the '099 Patent)**

111. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 110 of the Counterclaims as if fully set forth herein.

112. The claims of the '099 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

113. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '099 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

114. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '099 patent.

115. Cipla is entitled to a judicial declaration that all claims of the '099 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Ninth Counterclaim**
**(Declaratory Judgment of Noninfringement of the '013 Patent)**

116. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 115 of the Counterclaims as if fully set forth herein.

117. Counterclaim Defendants have accused Cipla of infringing the '013 patent.

118. Cipla denies infringement of the '013 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '013 patent.

119. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of

sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '013 patent.

120. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '013 patent.

**Tenth Counterclaim**
**(Declaratory Judgment of Invalidity of the '013 Patent)**

121. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 120 of the Counterclaims as if fully set forth herein.

122. The claims of the '013 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

123. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '013 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

124. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '013 patent.

125. Cipla is entitled to a judicial declaration that all claims of the '013 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double

patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Ninth Counterclaim**
**(Declaratory Judgment of Noninfringement of the '209 Patent)**

126. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 125 of the Counterclaims as if fully set forth herein.

127. Counterclaim Defendants have accused Cipla of infringing the '209 patent.

128. Cipla denies infringement of the '209 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '209 patent.

129. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '209 patent.

130. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '209 patent.

**Tenth Counterclaim**
**(Declaratory Judgment of Invalidity of the '209 Patent)**

131. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 123 of the Counterclaims as if fully set forth herein.

132. The claims of the '209 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not

limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

133. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '209 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

134. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '209 patent.

135. Cipla is entitled to a judicial declaration that all claims of the '209 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

**Request for Relief**

WHEREFORE, Cipla requests that this Court enter judgment against Counterclaim Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not and will not directly or indirectly infringe any claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the Patents-in-Suit are invalid and/or unenforceable;

C. Ordering that Counterclaim Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Cipla;

D. Preliminarily and permanently enjoining Counterclaim Defendants, its employees and agents, and any other person acting in concert with any of them, from asserting or threatening to assert any alleged rights arising under the Patents-in-Suit against Cipla or any person or entity working in concert with Cipla;

E. Awarding Cipla its costs and expenses incurred in this action;

F. Declaring that this is an exceptional case in favor of Cipla and awarding Cipla its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

G. Awarding Cipla such other and further relief as the Court may deem proper.

DATED: January 17, 2024

**K&L GATES LLP**

By: */s/ Loly G. Tor*
Loly G. Tor (loly.tor@klgates.com)
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4026
(F) 973.848.4001

Of Counsel:

Devon C. Beane
(devon.beane@klgates.com)
(*pro hac vice*)
Ewa A. Wojciechowska
(*pro hac vice*)
**K&L Gates LLP**
70 West Madison Street, Suite 3300
Chicago, IL 60622
(T) 312.372.1121
(F) 312.827.8000

Anil H. Patel (anil.patel@klgates.com)
(*pro hac vice*)
**K&L Gates LLP**
609 Main Street, Suite 4150
Houston, TX 77002
(T) 713.815.7300
(F) 713.815.7301

Peter Giunta (peter.giunta@klgates.com)
**K&L Gates LLP**
599 Lexington Avenue
New York, NY 10022
(T) 212.536.3900
(F) 212.536.3901

Harold Storey (harold.storey@klgates.com)
(*pro hac vice*)
Jenna Bruce (jenna.bruce@klgates.com)
(*pro hac vice forthcoming*)
**K&L Gates LLP**
925 Fourth Avenue, Suite 2900
Seattle, WA 98104
(T) 206.623.7580
(F) 206.623.7022

*Attorneys for Defendants/Counterclaim-Plaintiffs Cipla Ltd. and Cipla USA, Inc.*

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Under Local Civil Rule 11.2, the undersigned counsel for Cipla Ltd. and Cipla USA, Inc. hereby certifies that, to the best of my knowledge, the following actions involve the same U.S. Patent Nos. as the instant action:

- *Theravance Biopharma R&D IP, LLC et al v. Accord Healthcare, Inc. et al.*, 1-23-cv-00157 (MDNC) (Filed Feb. 17, 2023);
- *Theravance Biopharma R&D IP, LLC et al v. Lupin Inc. et al.*, 1-23-cv-00187 (DDE) (Filed Feb. 17, 2023); and
- *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Ltd. et al.*, Consolidated Case No. 2:23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

I further certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. I certify under penalty of perjury that the foregoing is true and correct.

Dated: January 17, 2024

*/s/ Loly G. Tor*
Loly G. Tor

**LOCAL CIVIL RULE 201.1 CERTIFICATION**

Under Local Civil Rule 201.1, the undersigned counsel for Cipla Limited and Cipla USA, Inc. hereby certifies that this action involves a request for injunctive relief and therefore is not appropriate for compulsory arbitration.

Dated: January 17, 2024

*/s/ Loly G. Tor*
Loly G. Tor

Loly G. Tor
(loly.tor@klgates.com)
**K&L Gates LLP**
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4026
(F) 973.848.4001

*Attorneys for Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.*

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

THERAVANCE BIOPHARMA R&D IP, LLC, THERAVANCE BIOPHARMA US, INC., THERAVANCE BIOPHARMA IRELAND LIMITED, MYLAN IRELAND LIMITED, and MYLAN SPECIALTY L.P.,,

Plaintiffs,

v.

EUGIA PHARMA SPECIALITIES LTD., EUGIA US LLC, AUROBINDO PHARMA USA, INC., AUROBINDO PHARMA LIMITED, MANKIND PHARMA LTD., LIFESTAR PHARMA LLC, ACCORD HEALTHCARE, INC., MEDICHEM S.A., MEDICHEM MANUFACTURING (MALTA) LTD., MEDICHEM USA, LLC, LUPIN INC., LUPIN PHARMACEUTICALS, INC., ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED, CIPLA LIMITED, and CIPLA USA, INC.,,

Defendants.

Case No. 1:23-cv-00926-KMW-AMD

Hon. Karen M. Williams, U.S.D.J
Hon Ann Marie Donio, U.S.M.J

**CERTIFICATE OF SERVICE**

*Document Electronically Filed*

**LOLY G. TOR**, of full age, hereby certifies as follows:

1. I am an attorney-at-law of the State of New Jersey and admitted to practice before the United States District Court for the District of New Jersey and partner with the law firm of K&L Gates LLP, attorneys for Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.

2. I hereby certify that on the date indicated below, I caused a copy of Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.'s Answer to Plaintiffs' First Amended Consolidated Complaint, Separate Defenses, and Counterclaims, and this certificate of service to be served upon all counsel of record by CM/ECF.

3. I certify under penalty of perjury that the foregoing is true and correct.

Dated: January 17, 2024

*/s/ Loly G. Tor*
Loly G. Tor